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THE ASSESSMENT AND REHABILITATION OF POST STROKE DYSPHAGIA

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Abstract

Comprehensive Screening Tests

Post stroke dysphagia is common and requires accurate screening to identify patients that need further assessment and management. Nurses and other non-specialists in dysphagia are often trained to screen swallowing post-stroke. In addition to screening for dysphagia more comprehensive screening tests allow non-specialists to recommend modified oral intake. Little is known about the accuracy, clinical utility and cost effectiveness of these tests.

A systematic review and meta-analysis were conducted to describe the comprehensive swallow screening tests that are available for use in acute stroke by nurses or other non-specialists. The review also evaluated the accuracy, clinical utility and cost effectiveness of these tools. In a prospective study, one of these comprehensive screening tests, the Dysphagia Trained Nurse Assessment (DTNAx) was validated against usual SLT assessment and videofluoroscopy with 47 acute stroke patients. This thesis also aimed to find out the experiences of Dysphagia Trained Nurses (DTNs) by carrying out semi-structured interviews with nine nurses.

Five comprehensive screening tests for dysphagia were identified, but validation studies were mostly low or very low quality. Three studies validating the Gugging Swallow Screen provided sufficient data for meta-analysis, demonstrating high sensitivity; 96% (95%CI 0.90-0.99) but lower specificity, 65% (95%CI 0.47-0.79). The DTNAx was superior to the other tests in its safety and content validity. In its subsequent validation, compared to the SLTAx in the identification of dysphagia, the DTNAx had a sensitivity of 96.9% (95% confidence intervals CIs 83.8%-99.9%) and specificity 89.5% (95% CIs 75.2%-97.1%). Compared to the VFS in the

identification of aspiration, the DTNAx had a sensitivity of 77.8% (CIs 40.0%-97.2%) and specificity 81.6% (CIs 65.7% to 92.3%). Over 81% of the diet and fluid recommendations made by the DTNs were in absolute agreement with the SLTAx. Dysphagia Trained Nurses reported high regard for the role and gave useful insights into the challenges that arise in the busy acute stroke unit.

Biofeedback in dysphagia rehabilitation

Ongoing dysphagia can have detrimental effects on physical and mental health post stroke. SLTs conduct more detailed assessments and provide rehabilitation to patients with persistent dysphagia. The use of biofeedback is beneficial in stroke rehabilitation and is gaining ground as an adjunct in the field of dysphagia rehabilitation but there are no robust studies of its effectiveness or feasibility in the acute stroke setting.

A second systematic review and meta-analysis investigated the evidence on the effects of swallow therapy augmented by biofeedback in adults with dysphagia. Finally, a randomised controlled feasibility study into swallow strength and skill training with surface electromyography (sEMG) biofeedback in 27 acute stroke patients with dysphagia was performed.

Only 23 studies were identified that investigated biofeedback as a dysphagia intervention, of which three main types were reported: surface electromyography, accelerometry and tongue manometry. Five controlled studies were included in the meta-analyses. Compared to the control, biofeedback augmented dysphagia therapy enhanced hyoid displacement significantly (three studies, MD=0.22cm; 95% CI [0.04, 0.40], p=0.02) but there was no significant difference in functional oral intake. Risk of bias was high and there was significant statistical heterogeneity.

The RCT demonstrated feasibility and acceptability in participants recruited; 11 out of the 13 participants in the intervention group completed the treatment (>80% of sessions). The planned recruitment target was not met and would need to be mitigated for in future studies. Most participants found the intervention challenging but comfortable and the right duration, frequency and time post stroke. There were no related serious adverse events. There were no significant differences between groups in Functional Oral Intake Scale (FOIS), Dysphagia Severity Rating Scale (DSRS) and Penetration Aspiration Scale (PAS) at 2-weeks or at 90 days.

Conclusions

Using the DTNAx, trained nurses can screen acute stroke patients for dysphagia accurately and make early swallowing recommendations in line with SLTs. Further research is needed to investigate the clinical utility and cost effectiveness of this versus other swallow assessment pathways in acute stroke. Swallow strength and skill training with sEMG biofeedback is feasible and acceptable to acute stroke patients with dysphagia. It is safe and it may improve post stroke dysphagia. Further research investigating approaches to intervention delivery, treatment dose and effectiveness is indicated.

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List of Abbreviations

ASU	Acute Stroke Unit
BESST	Bedside Swallow Screening Tool
BI	Barthel Index
BiSSkiT	Biofeedback in Strength and Skill Training
BLR	Binary logistic regression
CI	Confidence Intervals
CONSORT	Consolidated Standards of Reporting Trials
COREQ	Consolidated criteria for Reporting Qualitative research
CTAR	Chin tuck against resistance
DHI	Dysphagia Handicap Index
DSRS	Dysphagia Severity Rating Scale
EMST	Expiratory muscle strength training
FEES	Fibreoptic Endoscopic Evaluation of Swallowing
FOIS	Functional Oral Intake Scale
GOTT	Global oral transit time
GUSS	Gugging Swallow Screen
HSROC	Hierarchical summary receiver operating characteristic
ICC	Intraclass correlation coefficient
ICH	Intercranial haemorrhage
IDDSI	International Dysphagia Diet Standardisation Initiative
LACS	Lacunar stroke
MBSImP	Modified Barium Swallow Impairment Profile
MD	Mean difference
MDT	Multidisciplinary Team
MLR	Multiple linear regression
mRS	Modified Rankin Scale
NBM	Nil by mouth
NG	Nasogastric tube
NICE	National Institute for Health and Care Excellence
NIHSS	National Institute of Health Stroke Scale
NMES	Neuromuscular electrical stimulation
NPV	Negative predictor value
OLR	Ordinal logistic regression
OR	Odds ratio
PACS	Partial anterior circulatory stroke
PAS	Penetration Aspiration Scale
PEG	Percutaneous endoscopy gastrostomy
POCS	Posterior circulatory stroke
PPV	Positive predictor value
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QOL	Quality of life
QUADAS	Quality Assessment of Diagnostic Accuracy Studies
RCP	Royal College of Physicians

RCSLT	Royal College of Speech and Language Therapists
RCT	Randomised controlled trial
ROC	Receiver operating characteristic
SD	Standard deviation
SDSS	Signs of Depression Scale
sEMG	Surface Electromyography
SLT	Speech and Language Therapist
TACS	Total anterior circulatory stroke
TOR-BSST	Toronto Bedside Swallowing Screen Test
UES	Upper oesophageal sphincter
VFS	Videofluoroscopy
VVST	Volume Viscosity Swallowing Test
WST	Water swallow test
2v/3t-P	2 Volume, 3 texture test

Chapter 1: Introduction

1.1 Overview

The introduction aims to give a comprehensive review of the literature around swallowing and dysphagia and how this presents in stroke. It describes the current evidence around screening and assessment of dysphagia and treatments for dysphagia.

1.2 Swallowing

Swallowing is a complex sensorimotor function that has a number of purposes; the ingestion of food and fluids and the clearance of the pharynx and larynx in protection of the airway. The oropharyngeal swallow involves a complex combination of six cranial nerves, three cervical nerves and over 30 pairs of muscles [1]. The swallow is often separated into the pre-oral stage, oral stage, pharyngeal stage and oesophageal stage. Pre-oral stage is everything that happens before the food or drink enters the mouth, seeing the food, smelling the food, appetite and getting the food to the mouth. The oesophageal stage transfers the bolus posteriorly to the lower oesophageal sphincter and stomach via peristalsis – a wave of muscle constriction and relaxation. Oropharyngeal dysphagia is the main focus of this thesis.

1.2.1 Oral stage

The oral stage is responsible for preparing the food/liquid for swallowing. It involves muscular control of the lips, the buccinators and the posterior tongue and palate to contain the food/liquid in the oral cavity and prevent anterior or posterior spillage [2]. Food requires mastication which involves a basic rhythmic motor action from muscles of the jaw controlled by a central pattern generator located in the brainstem. This basic pattern is modulated by

information received from sensory pathways peripherally and via the cortex dependent on the characteristics of the food [3]. Sensory and cortical information also trigger a brainstem response for watery, amylase rich saliva to be secreted mainly by the parotid gland. This combines with the food to form a cohesive bolus, aids transition down the digestive tract and begins the process of digestion [4]. The final part of the oral stage is bolus transfer to the pharynx, and initiation of the pharyngeal stage.

Mendell and Logemann summarise that for fluids the lips close first followed by jaw elevation. The tongue position allows the bolus to collect anteriorly in front of the tongue or posteriorly on the tongue dorsum before being transferred posteriorly. Timings are highly variable between individuals and onset of the processes increases with age and bolus size [5]. Several definitions of oral to pharyngeal transfer have been used to measure timings. Oral Transition Time OTT - the time interval in seconds from onset of tongue movement propelling the bolus posteriorly until the bolus head passes the ramus of the mandible was found to be 0.35-0.4s in healthy non-dysphagic adult women[6]. Similar results were found by Dantas and colleagues, but the definition of oral transit time was not specified [7]. Oral transition duration OTD - beginning of posterior movement of the bolus to the bolus head at ramus of mandible was found to be 0.41-0.53s in healthy adults [8]. Longer oral ejection times (0.81) were found when this was classified as the length of time it took the bolus to move through the oral cavity from the first frame showing the tongue tip touching the palate until the bolus tail passed the fauces [9].

When a solid bolus enters the oral cavity, it is transferred posteriorly past the canines for chewing (Stage I transport) [9]. Number of chews is relative to the texture and size of the bolus [10]. During the chewing phase, chewed food may be transferred back to the

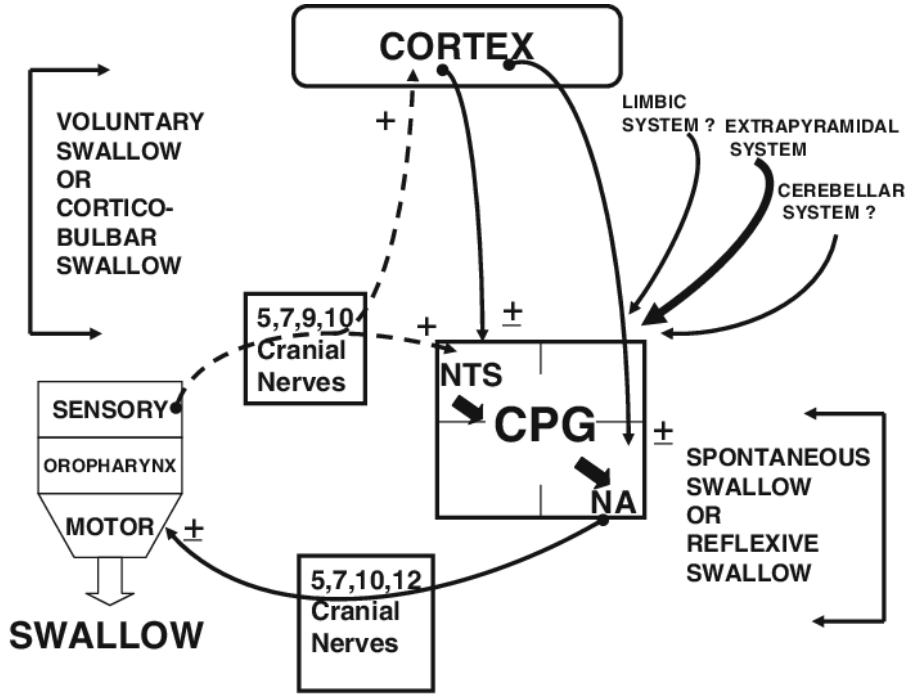
oropharynx or valleculae in several stages (Stage II transport) prior to oral propulsion that leads to the swallow onset [11].

1.2.2 Pharyngeal stage

The pharyngeal stage involves protection of the airway and effective bolus transfer to the oesophagus. The pharyngeal stage is considered to be a reflexive mechanism that once triggered is under involuntary control by the brainstem [12]. The swallow reflex can be triggered at rest involuntarily by the presence of saliva in the oral cavity [13]. The swallow is initiated and modulated by sensory information from the cortex and peripheral sensory pathways from the oral cavity, pharynx and larynx. It is thought that a central pattern generator (CPG) , located in the medulla oblongata controls the sequenced motor pattern that occurs when a pharyngeal swallow is triggered [14]. Electromyographic studies have shown initial activity in the mylohyoid muscle and then a few milliseconds later in pharyngeal and base of tongue muscles [14], it continues with the activation and inhibition of the muscles in the pharynx. As a result of these sequenced muscle actions the larynx elevates, the hyoid elevates and tilts anteriorly, the arytenoids make contact with the base of the epiglottis which deflects covering the laryngeal vestibule, the vocal folds and aryepiglottic folds close, the pharynx shortens and the cricopharyngeal sphincter relaxes to allow passage of the bolus into the oesophagus [15]. This process involves obligatory muscles that produce the basic reflex and extrinsic muscles that can be engaged and modulated by the CPG dependent on sensory [16, 17] and cortical [18, 19] information received. The cortical and sub-cortical swallowing network primarily includes the primary sensorimotor cortex, anterior cingulate cortex, premotor cortex, frontoparietal operculum, and insula [20]. Sensory information is postulated to converge on the nucleus tractus solitari (NTS); the glossopharyngeal (IX), vagal

(X) and facial (VII) afferent pathways directly synapse in the NTS and trigeminal afferent pathways connect indirectly via the trigeminal (Vth) sensory nuclei [12]. The NTS neurons are also referred to as the 'dorsal swallowing group'. Once sensory information has been processed signals are sent to the 'ventral swallowing group' for the motor output [12]. See Figure 1.1.

Figure 0-1: Cortical and brainstem control of swallowing – From [16]



CPG=Central Pattern Generator, NTS=Nucleus tractus solitari, NA=nucleus ambiguous

1.3 Dysphagia

1.3.1 Impairment

Dysphagia is an impairment in swallowing and can be caused by oral, pharyngeal or laryngeal structural changes, central or peripheral sensorimotor neurological damage, deconditioning, respiratory or psychological impairment [21]. A disorder in swallowing needs to be

distinguished from differences in swallow, given that what is normal varies considerably and changes as we age [22].

1.3.2 Prevalence

A population study in the US found that one in 25 adults had dysphagia [23]. Dysphagia is increasingly common in an ageing population with reports of symptoms occurring in up to 40% of adults over 65 [24]. Dysphagia can be caused by any condition affecting the structure, function or biomechanics of the oral or pharyngeal or laryngeal cavities. Age related changes in swallowing, or presbyphagia, such as reduced hyolaryngeal excursion, reduced masticatory efficiency and reduced sensory awareness have been well documented [25] but alone is not a cause for dysphagia. It is only in the presence of other conditions, an acute illness or frailty when there can be a clinically significant impact on the safety or efficiency of the swallow.

1.3.3 Consequences

One of the major consequences of dysphagia is airway penetration or aspiration – where saliva, food or fluids enter the airway prior to, during or after the swallow. This should result in a reflexive cough to clear the material. If no cough is present it is termed silent aspiration. If the cough is weak or absent and penetration/aspiration is of large volume or persistent over time, it can cause inflammation or infection of the lung [26]. A more serious consequence is aspiration pneumonia which can lead to greater mortality [27, 28] and length of hospital stay [29]. Further research is needed to qualify the contribution of different risk factors but dependency for oral care, reduced mobility and dependency for feeding along with dysphagia increase the risk of developing aspiration pneumonia[30]. Dysphagia can also lead to choking[31], dehydration and undernutrition [32, 33] and may require supplementation of or dependency on short or long term enteral feeding/hydration. People with dysphagia also

report reduced quality of life, meal avoidance, anxiety over mealtimes and reduced enjoyment of eating and drinking [34, 35].

1.4 Stroke

1.4.1 Definition

Stroke is defined by the interruption of blood supply to a part of the brain. This might occur due to a thrombotic or embolic occlusion of a cerebral artery or when a blood vessel haemorrhages into the spaces around brain cells. When the supply of oxygen or nutrients from the blood is interrupted brain cells can die, resulting in differing symptoms dependent on location of the stroke.

1.4.2 Incidence of stroke

Each year, over 100,000 people in the UK have a stroke. Around 85% are ischemic strokes; caused by a thrombotic or embolic occlusion of a cerebral artery. The remainder are haemorrhagic strokes; caused by bleeding from the intracerebral arteries [36].

1.4.3 Types of stroke and symptoms

Strokes are classified by the location; left or right and the blood vessels involved; anterior circulatory stroke, posterior circulatory stroke and lacunar stroke. Anterior circulatory strokes are further subdivided into total or partial, describing the extent of impairment from the stroke [37]. Stroke can cause physical, sensory, visual, cognitive, emotional, swallowing and language impairments. Patients may suffer pain, fatigue and lose control of their continence. Two thirds of patients leave hospital with a disability and about a third will experience depression as a result of their stroke [36].

1.4.4 Secondary complications

One in eight strokes are fatal within 30 days [36]. Secondary medical complications include further stroke [38], pneumonia, urinary tract infection, pressure ulcers, falls, deep vein thrombosis, pulmonary embolism, and severe constipation [29]. Stroke associated pneumonia (SAP) is common, occurring in 10% of patients [39]. Mortality is greater in patients with pneumonia; a threefold increase in death within 30 days compared to those without [28].

1.4.5 Pathway and MDT

The National stroke strategy 2007 [40] provided a quality framework and enabled the setting up of dedicated stroke units across the country, staffed by a trained multidisciplinary team including, doctors, nurses, allied health professionals, psychology, nursing and rehabilitation assistants. Access to specialist imaging, pharmacy, orthoptics, dietetics should also be available. The Royal College of Physicians (RCP) detailed National Clinical Guidelines for Stroke [41] aim to guide quality improvements across stroke services. The Stroke Sentinel National Audit Programme monitors the stroke services in achieving performance targets such as numbers of patients directly admitted to stroke units or CT scans within one hour of admission. Patients who benefit from rehabilitation may receive this in inpatient units or in their own homes. Although community stroke provision is highlighted as an area requiring improvement in the NHS Long Term Plan[42].

1.5 Stroke rehabilitation

1.5.1 Assessment/adaptation/education

In the hours and days following a stroke multidisciplinary intervention involves assessment, patient and family education and finding immediate adaptations where possible so the patient can retain as much independence as possible. Therapists make goals with the patient to work towards restoring function through therapeutic intervention which may vary in approach.

1.5.2 Restoration of function and neuroplasticity

True restoration of damaged cortex is impossible without use of stem cells. Therefore the neural recovery that occurs is mostly by other parts of the cortex acquiring the lost function and neural pathways forming new connections much in the same way that occurs in experience dependent neuroplasticity in neural development [43]. Neurons in the peri-infarct cortex undergo structural and functional remodelling when possible but in larger strokes it may be further away and even in the contralateral hemisphere. Gene expression and neurotransmitters present post stroke may contribute to optimising the conditions for neuroplasticity although this is possibly subject to a time window suggesting that early intervention is beneficial [44].

1.5.3 Optimising neuroplasticity

Kleim and colleagues summarised the findings from neuroscience and neuro-rehabilitation studies to highlight key factors to optimise neuroplasticity. Interventions need to be intensive, repetitive, salient, task specific [45] and progressively challenging [46]. Maier and colleagues added other factors such as spaced practice, variable practice, feedback, imagery and action

observation. But they found that clinical studies often used multiple methods making it difficult to evaluate contribution of specific factors [47].Potential for neuroplasticity reduces with ageing [45] and there is evidence that neuroplasticity is optimised in the early weeks post stroke [44].

1.5.4 Strength Training

Immediately post stroke there are little or no mechanical or structural changes within muscles, however with even a short period of immobilisation, with or without stroke, marked atrophy of skeletal muscle, fibrosis of the extracellular matrix and visco-hyperelastic parameter changes can be seen[48]. Although resistance and repetitive physical strength training has shown limited effects on mobility, balance and motor control, it has demonstrated that it can improve muscle strength and muscle force, quality of life, independence and reintegration[49]. These gains are believed to be due to central neuroplastic changes as well as peripheral muscle strengthening, but not generalised to improvement in functional tasks[50].

1.5.5 Task specific rehabilitation

Skill acquisition or re-acquisition is experience dependent. Training on a specific skill alters the motor pathways specific to the muscle groups involved in performing the task but repetitive muscle movements unrelated to the task does not produce the same results [50]. In animals, skilled training results in greater neuroplastic and functional changes than unskilled training [51]. In adults post stroke, task specific rehabilitation results in better functional outcomes than non-specific strength training [52]. Across stroke rehabilitation there has been a shift towards task specific therapy [53].

1.5.6 Feedback

Motor control and motor learning literature can help explain why the use of feedback has been considered as an adjunct to rehabilitation. A task, such as reaching for a glass of water, can be performed in many different ways – a phenomenon known as redundancy [54]. In order to improve task efficiency, optimal motor patterns are learnt. The appropriate optimal motor patterns are then selected based on sensory information received prior to executing the task (feedforward control). The motor pattern for reaching is modulated by the sensory information received about the distance and position of the glass before initiating the movement. Humans have the capacity to adapt patterns of movement in response to a disruption to the existing pattern or when the sensory information received during or following execution does not match the original motor plan (feedback control) [55]. Three different types of feedback are used in adjusting and optimising the series of movements to achieve an objective [56] . Internal intrinsic feedback relates to the state of our own body. Intrinsic external feedback informs us of the state of the external world. Such as in the action of us kicking a ball, we receive feedback to whether the motor plan we executed resulted in the ball entering in the goal. Extrinsic feedback informs us how we interacted with the world [55]. Augmented feedback is when intrinsic feedback is enhanced by an external source. This can be by a therapist giving verbal feedback about the performance of a task. Feedback can be either given as knowledge of their performance i.e. good or bad and/or by having knowledge of the result i.e. their actual score/power/amplitude. When this information is given based on kinematic measures it is called biofeedback.

1.6 Dysphagia and stroke

1.6.1 Incidence of dysphagia in stroke

Dysphagia, or difficulty with swallowing, affects around 55% of patients who have suffered a stroke [57].

Total anterior circulatory strokes (TACS) are more likely to present with dysphagia [58]. Greater lesion volume results in more severe dysphagia [59]. Lesions in the sensorimotor cortex, insular [60] and internal capsule lesions [61] have all been found to be associated with dysphagia. Dysphagia also needs to be considered in brainstem strokes. About 50% of patients with lateral medullary lesions have dysphagia [62] and pontine strokes are good predictors of dysphagia [63].

1.6.2 Outcomes of stroke patients with dysphagia

Dysphagia in stroke increases the risk of aspiration pneumonia [57] and results in increased mortality, increased length of stay [64] and an increased chance of admission to a nursing home on discharge [65]. Approximately 10% of stroke patients have chronic, persistent dysphagia [66, 67] Longer term impacts include tube feeding, risk of malnutrition and reduced quality of life affecting patients with chronic dysphagia post stroke [26].

1.6.3 Typical characteristics of dysphagia in stroke

Post stroke dysphagia can affect the oral stage and the pharyngeal stages. See Table 1.1

Table 0-1: Oral and Pharyngeal stage impairments following stroke

Oral stage impairments:	**Pharyngeal stage impairments:**

• Delayed initiation of motor movements [68]
• Reduced oral sensation [69]
• Impaired tongue control [70, 71] responsible for manipulation of the bolus within the oral cavity, posterior transfer, oral clearance
• Reduced efficiency of mastication – increased duration of oral phase[72]
• Buccal neglect [73]
• Reduced salivary flow/dry mouth - possibly secondary to medications [72]
	• Delayed initiation of hyolaryngeal excursion:
	  ○ Delay in initiation of laryngeal closure (ILC) [74, 75]
	  ○ Prolonged stage transition duration (STD) from the bolus at ramus of the mandible until initiation of hyoid excursion. [76].
	• Delayed closure of the laryngeal vestibule [77]
	• Slower movement velocity of the larynx, hyoid and epiglottis (Seo, Oh, & Ryoon Han, 2016)
	• Sensory impairment of the laryngopharynx [78]
	• Impaired vocal cord mobility [79]
	• Reduced pharyngeal motility [70]
	• Impaired UES opening [80]

1.7 Dysphagia assessment

1.7.1 History

In the United Kingdom (UK) since the 1980s Speech and Language Therapists (SLTs) have a primary role in the assessment and management of oropharyngeal dysphagia. By the 1990s the Royal College of Speech and Language Therapists (RCSLT) recognised the pressure this demand put on services, as well as that from SLTs existing communication caseloads. As a result, there was a recognition for the need for a multidisciplinary approach to dysphagia and since then different approaches to this have emerged [81].

1.7.2 Why it is necessary?

The RCP National clinical guideline for stroke, endorsed by the National Institute for Health and Care Excellence (NICE), provides guidelines for the management of swallowing and nutrition post-stroke with the aim to reduce the negative health and psychosocial consequences of dysphagia. All patients admitted with a new stroke should be kept Nil By Mouth (NBM) until a swallowing assessment by a trained professional has been carried out using a validated tool [41]. Early assessment of swallowing is associated with reduced stroke associated pneumonia [82, 83]. A recent systematic review concluded that early screening using a formal protocol and early involvement by SLT reduced the risk of post stroke pneumonia [84].

1.7.3 Assessment process

Considering that all new stroke patients are recommended to be assessed within four hours, it would rely on having access to dysphagia trained professionals 24 hours a day, 7 days a week. Training nurses to conduct swallowing assessments has demonstrated that patients can be assessed within the recommended time frame [85] and that nurses are an essential part of the multidisciplinary team (MDT) management of dysphagia. The Interprofessional Dysphagia Framework promotes the use of trained professionals to manage dysphagia by setting out a series of levels of competence [86]. Most nurses who assess or screen for dysphagia would be trained to a Foundation Dysphagia Practitioner level and would be trained to follow a protocol led assessment once achieving the specified competencies. These protocols may be in the form of a basic *swallow screen* that requires little training, that may include water trials and results in a yes/no to the presence of dysphagia. Those that pass can commence normal oral intake whilst those who fail remain NBM. Other protocols,

comprehensive swallow screening tests may be more comprehensive and whilst still following a strict proforma, additional sections can be included, such as an oromotor screen and oral trials of different consistencies of liquids and diet in addition to water. Such protocols would allow some compensatory recommendations to be made if a patient is identified with less severe dysphagia. In clinical practice many different screening tools exist, offering different amounts and consistencies of oral intake, many have not been validated to assess for accuracy [87].

1.7.4 Swallow screening

1.7.4.1 Non swallow tests

Basic screens comprise a series of questions regarding alertness and neurological function. Two examples were found to have sensitivity greater that 80% in a systematic review [88]. These were the Modified Mann Assessment of Swallowing [89] and Emergency Physicians Swallow Screen [90] designed to be administered by Stroke Physicians.

1.7.4.2 Water swallow tests

Water swallow screens comprise a basic alertness/neurological screen and the patient is asked to swallow varying amounts of water, differing from test to test from teaspoons, sips and consecutive sipping. A systematic review on swallowing screening tests in stroke showed that a range of different water swallow test protocols had sensitivity for aspiration of between 37% and 80% when verified on instrumental assessment [91]. In the Schepp review [88] only two water swallow screening tests were found to have adequate (>80%) sensitivity, namely the Toronto Bedside Swallowing Screen Test (TOR-BSST) [92] and the Barnes Jewish Hospital Swallow Screen [93].

Much work has been done to identify the most sensitive predictors for aspiration from clinical assessment [94, 95]. In a systematic review of validity of individual screening items Martino and colleagues found that pharyngeal sensation, tongue movement and baseline voice quality were good neurological predictors of aspiration. Whilst dysphonia or coughing during/after a 50 ml water test were good clinical predictors of aspiration [94]. Brodsky and colleagues compared the validity of the amounts and methods of delivery of water in a systematic review of water swallow tests. They found consecutive sips of greater than 90ml water produced high sensitivity and single sips of water produced high specificity. Therefore, achieving both high sensitivity and specificity in the same assessment may be impossible [95]. So, for screening tests, achieving high sensitivity is most important.

The majority of the screening tools have been validated against the detection of aspiration on instrumental assessment. Aspiration is one of the consequences of dysphagia. Other consequences are choking, malnutrition and dehydration. Only one of the good quality studies has validated a tool against videofluoroscopy for the detection of dysphagia, the TOR-BSST which achieved sensitivity of 91% and specificity of 66% [92].

It may be that 100% sensitivity is not possible due to silent aspiration which is believed to occur in 15-39% of people who have had a stroke due to sensory impairment. Consistent with the literature already discussed larger bolus volumes in water swallow tests identify more individuals who silently aspirate on small volumes [96].

With high sensitivity in the screening tests, comes a high number of false positives [88, 91, 94, 95]. Clinically this results in patients who are not at risk of aspiration or dysphagia remaining NBM until they are assessed by a Speech and Language Therapist. No oral intake and tube feeding increase risks of aspiration due to poor oral health and reflux and it can have detrimental effects on swallowing [97, 98].

1.7.4.3 Comprehensive swallow screening tests

To avoid newly admitted acute stroke patients remaining NBM and having NG tubes unnecessarily, diet or fluid modification is one way of commencing safe oral intake with some of these patients. The theory and evidence behind fluid and diet modification as compensatory/adaptive techniques and the International Dysphagia Diet Standardisation Initiative levels (IDDSI) will be discussed Section 1.8.1. The recommendation of modified diet/fluids can be incorporated into a more comprehensive assessment protocol that a trained Foundation Dysphagia Practitioner can use. Few comprehensive swallow screening assessment tools have been published, and no such review or comparison of these tools has been conducted. The most published tool is the Gugging Swallowing Screen (GUSS). This tool carried out by nurses has been validated against Fibre-optic Endoscopic Evaluation of swallowing with a sensitivity of 100% and specificity of 69%. However, these results have to be taken with caution as numbers were small (N=30), reliability was only conducted with SLTs carrying out the test and all the patients included were previously identified as having dysphagia. The tool has since been validated in a number of other studies with different methodologies.

i) Introduction of the Dysphagia Trained Nurse Assessment

Another tool first described in 2001, originally named 'Screening for dysphagia' but subsequently known as the Dysphagia Trained Nurse Assessment (DTNAx) was developed in response to the increasing demand on SLTs for assessing dysphagia [81]. Originally it was used by Dysphagia Trained Nurses (DTNs) in acute and community services to screen for dysphagia, recommend safe diet and fluid recommendations and refer to SLT where dysphagia was complex or present for more than seven days[99]. After its introduction, an audit of the scheme demonstrated a reduction in number of days spent NBM by 45% and time

to assessment reduced [81]. The scheme has changed over time and now only acute stroke nurses are trained to be DTNs. The tool (Appendix 1) has also been updated to incorporate recent research and the transition to IDDSI terminology.

ii) Content Validity of the DTNAx

The DTNAx demonstrates strong content validity as the sub-assessments and components of the DTNAx are all evidenced based. The pre-screening checklist ensures that patients who are at higher risk of dysphagia or aspiration due to reduced alertness[30], history of dysphagia, presence of a tracheostomy or laryngectomy[100], requirements of >2L oxygen are not assessed [101]. It also ensures patients are sitting upright and have received mouthcare if required which reduces risk of aspiration and aspiration pneumonia[102].

The second part of the assessment is an oromotor and non-swallow assessment, during the DTN training the nurses are taught to be alert to any abnormalities in the patient's presentation as these are predictors of dysphagia and aspiration. Oromotor assessments are often included in clinical bedside assessments carried out by SLTs for these reasons [103]. Specific components have been found to be predictors of aspiration (Table 1.2), the components that are common between previous studies [104-107]; dysarthria, secretions, dysphonia and abnormal cough are included in the DTNAx.

The oromotor/non-swallow section is not a pass or fail; the test continues to the swallow assessment. This begins with a water swallow test from half teaspoons, full teaspoons, single sips and then 100ml drinking naturally. Beginning with small volumes increases specificity and assessing larger volumes increases sensitivity in identification of aspiration[108]. At each stage if no laryngeal elevation is felt the assessment is stopped and the patient remains NBM until SLT assessment.

Table 0-2 Content Validity of the DTNAx: comparing components to those identified as the best predictors for aspiration in previous studies.

Items	**McCullough 2001**	**Daniels 1998**	**Logemann 1999**	**Lee 2015**	**Brodsky 2016 SR of WSTs**	**DTNAx**
Preliminary checks						
Alertness			Y			Y
Poor comprehension				Y		
Distractible			Y			
Denies dysphagia			Y			
Pneumonia	Y					Y
Non swallow assessment						
Apraxia			Y			
Reduced oral sensation			Y			
Dysarthria	**Y**	**Y**	**Y**			**Y**
Oromotor impairment			Y			Y
Intelligibility	Y					Y
Secretions	**Y**		**Y**			**Y**
Wet voice	Y					Y
Impaired resonance	Y					
Dysphonia	**Y**	**Y**		**Y**		**Y**
Abnormal gag		Y				
Abnormal cough		**Y**		**Y**		**Y**
Items included in WST						
Single sips					**Y**	**Y**
Consecutive sips from large volumes					**Y**	**Y**
Signs on swallow test						
Cough on trials	**Y**		**Y**		**Y**	**Y**
Perception of P/A	**Y**			**Y**		**Y**
Voice change on swallow		**Y**	**Y**		**Y**	**Y**
Reduced laryngeal elevation			Y			Y
Multiple swallow			Y			
Oral residue			Y			Y
Swallow delay			Y			Y

Bold = items present in at least two other studies. SR = systematic review. WST = water swallow test. P/A = Penetration or Aspiration.

If any of the predictors of aspiration found in previous studies [104-107] are present; changes to breathing or voice quality, presence of a cough or a delay in swallow of greater than five

seconds are present the algorithm tells the assessor to move to the next section – thickened liquids. See section 1.8.1 for details on modified fluids and diet.

The assessment starts with six teaspoons and then sips of Level (L) 2 fluids and, as with thin liquids, if any predictors of aspiration are present the assessment moves on to six teaspoons and sips of L3 fluids.

If there are predictors of aspiration on teaspoons of L3 fluids the assessment is stopped and the patient remains NBM until SLT assessment. Due to variability of swallowing, testing more than three boluses per volume/consistency is recommended [109].

If fluid recommendations can be made, then the algorithm progresses to assessing diet textures. Beginning with five teaspoons of L4 diet, progressing through L5 and L6 to L7 diet, if no signs of aspiration or other impairment of safety or efficiency are identified.

In addition to the predictors of aspiration used for fluids, the test checks for oral residue, unchewed bolus or prolonged oral stage which may indicate other concerns over safety[106, 110] or efficiency[111]. A diet recommendation is made for the least modified diet consistency that showed no safety or efficiency concerns. In addition, DTNs are taught that if they have any concerns about the assessment, or lack of confidence in their recommendations they should keep the patient NBM and await an SLT assessment. The possible recommendations from the DTNAx are show in table 1.3.

The training has been strengthened to align with the Interprofessional Dysphagia Framework and now consists of a classroom theory session with a theory test, a practical hands-on session observing and conducting the DTNAx alongside an SLT and a final competency assessment. See table 1.4 for details.

Table 0-3 Possible recommendations from DTNAx

Fluid recommendations	**Diet recommendations**
L0 Normal fluids	L7 Normal diet
Teaspoons or sips L2 mildly thickened fluids	L6 Soft and bite sized diet
Teaspoons or sips L3 moderately thickened fluids	L5 Mince and moist diet
NBM	L4 Puree diet
	NBM

Table 0-4 Dysphagia Trained Nurse Training & Competency requirements

Stage of training	**Details**	**Time commitment**
Theory	Normal swallow Dysphagia Risks of dysphagia Signs of dysphagia Management of dysphagia Modification of diet and fluids DTN pathway DTN Assessment Multiple choice quiz	½ day
Practical	SLT demonstrates DTNAx on a patient with dysphagia DTN trainee carries out DTN with assistance from SLT	2-3 hours
Competency assessment	DTN trainee carries out DTNAx with SLT observing and using competency checklist	30 minutes (repeated if failed)
Update	Review of theory session, multiple choice quiz and Q&A	1 hour, 1-2 yearly

The benefits of training are that nurses have an increased understanding of dysphagia, increased ability to identify the signs and symptoms, increased compliance of staff to ensuring modified diets/fluids are provided and increased involvement in the needs of the patients around nutrition [112].

In summary there are a few good screening tools that demonstrate good accuracy for the identification of dysphagia in good quality validation studies. The DTNAx may well be superior in its content validity but has not yet been validated for diagnostic accuracy. A systematic

literature review to identify any other available tools is indicated, so that the content, applicability, accuracy and clinical utility of all the tools can be compared. Nurses' commitment to basic or more comprehensive screening and early management of dysphagia is important to ensure that the tools are used as intended. All patients in the pathway who meet the criteria are screened so that the prespecified recommendations are implemented as prescribed. Otherwise, the accuracy found in the validation studies will not be upheld. Little is known about how nurses value this role, their training, or the tool they use to screen for dysphagia or how committed they are to using it as specified or if there are deviations from its intended use.

1.7.5 Clinical Bedside Assessments (CBAs)

The aims of the CBA, carried out by trained SLTs, are to assess the safety of swallowing, to describe the nature of the impairment and consider management options for the patients with dysphagia.

Martino and colleagues found no CBAs that had undergone robust validation [113]. Most individual SLTs and services have their own methods of assessing swallowing based on knowledge from training and experience [114]. Their assessments usually include: taking a history, making an assessment of the motor and sensory function of the structures involved in swallowing, carrying out trials of different diet and fluid textures and undertaking trials of compensatory strategies [103]. The safety and efficiency of swallowing is considered when trialling different textures and compensatory strategies to find the safest, most efficient and least restrictive means. Whilst considering the patient's wishes and other aspects of their clinical presentation.

Objective assessment methods have been considered to identify those patients at risk of silent aspiration. Changes in oxygen saturation levels during swallowing using pulse oximetry has not been found to be effective in identifying aspiration, with a positive predictive factor as low as 39% [115]. Cervical auscultation, has also been considered as a tool to assess dysphagia and identify aspiration, although it has been found to have poor reliability and validity [116]. The Cough Reflex Test CRT is a tool to identify those at risk of silent aspiration by the judgement of response to the administration of nebulised tussive agents such as citric acid. It is designed to be carried out before the CBA and those who fail are thought to be at risk of silent aspiration and should undergo instrumental swallowing assessment [117]. Sensitivity and specificity are no greater than other assessments, around 69-81% and 60-71% respectively [117, 118].

To understand the specific swallowing impairment, to identify and quantify aspiration, to judge the effectiveness of strategies or make recommendations for exercises, CBAs are not reliable [119]. However, instrumental assessment can contribute more information.

1.7.6 Instrumental assessment

Gold standard assessments are Videofluoroscopy (VFS) and Fibreoptic Endoscopic Evaluation of Swallowing (FEES). However none of the published tools designed to analyse swallowing using VFS and FEES have robust validation and reliability[120]. Newer assessment techniques are emerging such as manometry, ultrasound, high resolution cervical auscultation and accelerometry, but are not yet or not often used in clinical practice.

1.7.6.1 Videofluoroscopy

VFS captures a series of x-ray images focusing on the oropharyngeal physiology while the patient swallows radiopaque boluses of different consistencies. VFS can be analysed frame by

frame to measure the biomechanic and kinematic processes of the swallow and to identify and differentially diagnose any impairment of swallowing. Although in-depth analyses such as these are usually only used in research. Clinically, various rating scales which measure safety (penetration and aspiration) and efficiency (residue) are most commonly used whilst standardised assessment tools which describe swallow impairment are less commonly used [121]. These include the Modified Barium Swallow Impairment Profile (MBSImP) which is a standardised assessment and analysis tool that requires users to achieve 80% reliability before being signed off as competent[122] and the New Zealand Index for Multidisciplinary Evaluation of Swallowing is another but is unpublished [123].

1.7.6.2 Fibreoptic Endoscopic Evaluation of Swallowing

FEES involves the trans nasal insertion of a fibreoptic nasoendoscope to the level of the oropharynx/ hypopharynx to evaluate laryngopharyngeal physiology, the management of secretions and the ability to swallow food and fluids. In both assessments aspiration or residue can be reliably identified and classified using rating scales so that the effectiveness of diet/fluid modification and use of compensatory strategies can be assessed.

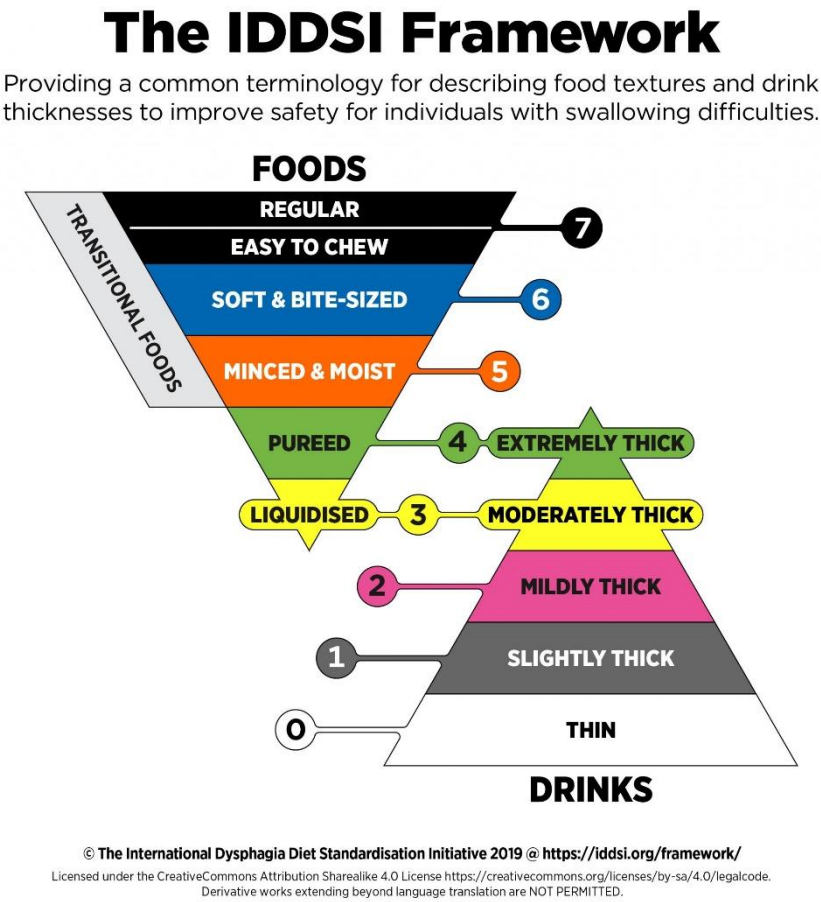
1.8 Rehabilitation of dysphagia

1.8.1 Diet adaptation

Although the long-term aim would be to enable a patient with dysphagia to return to eating and drinking normally, the immediate aim would be to commence safe oral intake where possible. Therefore, following assessment, SLTs recommend modifications to diet and fluids and compensatory strategies to achieve this. Where patients have poor oral control or a delayed swallow, thickened fluids have been shown to reduce risk of aspiration [124]. Food

can be pureed, softened or mashed so that chewing and swallowing are safer and more efficient[111]. The International Dysphagia Diet Standardisation Initiative (IDDSI) was introduced in 2016[125] Figure 1.2.

Figure 0-2 International Dysphagia Diet Standardisation Initiative IDDSI



Evidence that SLT recommendations for dietary modification and compensatory strategies are beneficial is lacking, but one randomised controlled trial (RCT) showed that it reduced pneumonia and improved swallow outcomes compared to physician care[126].

1.8.2 Compensatory strategies

Strategies such as effortful swallow and chin tuck have also been shown to prevent aspiration or risks of aspiration – see table 1.4 for more examples of strategies and the desired outcome. However, studies are small and results have been inconsistent, contradictory or can even cause greater impairments in patients [119, 127]. These strategies should always be trialled during instrumental assessment so their effects can be objectively evaluated.

Table 0-5 Compensatory strategies recommended in the management of dysphagia.

Strategy	Desired effect	Reference
Chin tuck	Decrease the depth of airway penetration Increase duration of laryngeal vestibule closure	[127] [128]
Head turn	Prevent bolus from passing down impaired side Increase pharyngeal pressure Increase duration of UES relaxation	[129]
Effortful swallow	Increase orolingual pharyngeal pressure Increase hyolaryngeal elevation Increase in duration of UES opening	[130]
Supraglottic swallow & Super-supraglottic swallow	Increase airway closure Earlier UES opening	[131]
Mendelson manoeuvre	Increase time of hyolaryngeal elevation Increase UES opening	[132]
Head back	Use gravity to move bolus towards pharynx	[21]
Second or clearing swallows	Clear residue from the oral or pharyngeal cavities	[21]

For some patients, more so in the post-acute phase, diet or fluid modification or tube feeding are not acceptable and may result in other risks such as reduced nutrition and hydration, or reduced quality of life[133]. SLTs work with patients to help them understand the benefits and risks of different options, find acceptable compromises or acknowledge that patients may

choose to eat and drink normally accepting these risks. Texture modification and the use of strategies are not a long-term solution. Therefore, alongside adaptation, SLTs aim to help rehabilitate the swallowing in the form of exercise, sensory stimulation and newer techniques such as brain stimulation. The focus in this thesis will be on swallowing exercises.

1.8.3 Strength based training

Non task-specific strength training focusing on strengthening individual muscles or groups of muscles has been the focus in interventions for dysphagia [134]. Exercises are usually recommended after instrumental assessment has identified a specific weakness, or reduced range of movement in a muscle or muscle group. These include isometric anterior and posterior tongue exercises and the head lift exercise (HLE), chin tuck against resistance (CTAR) and expiratory muscle strength training (EMST) aimed at targeting suprahyoid muscles. Although gains in tongue strength have been found, tongue exercises have not been robustly demonstrated to improve swallow function [135]. EMST resulted in significantly reduced liquid aspiration when compared to sham in a small post stroke dysphagia RCT and further research is indicated [136]. In two small RCTs the HLE has been shown to increase cricopharyngeal sphincter opening, hyoid excursion, reduce aspiration and improve functional swallowing (Shaker et al., 2002)[137]. Although another study showed that there was no functional improvement in swallowing following the Shaker program (Logemann et al., 2009). CTAR has also been shown to reduce significantly aspiration and improve functional swallow compared to a control group. [138]. Other strength-based exercises require repetitive practice using a modified swallow as a strengthening exercise. These include the Mendelsohn manoeuvre, effortful swallow and supraglottic swallow manoeuvres, as mentioned above, but also includes tongue hold swallows also known as Masako [139].

Masako and supraglottic swallows have not been investigated as an intervention to date [140]. Only their immediate effects have been described (Table 2 above). Mendelson manoeuvre paired with biofeedback (see below) found greater improvements in swallow physiology over a control group but no functional outcomes [141]. In a small RCT the effortful swallow demonstrated significantly greater improvement in tongue strength and oral stage swallow measures on VFS than in a control group [142].

1.8.4 Thermotactile stimulation

Sensory stimulation in the form of thermal and tactile stimulation of the faucal arches in the oropharynx has also been used as a treatment aimed at increasing the oral and pharyngeal transit times of patients with delayed swallow onset [143]. However, the evidence supporting this is limited and thus the effectiveness questionable [144] and at best the technique may reduce the speed of swallow trigger if administered directly prior to swallowing [145]. In addition to mechanical stimulation, chemo stimulation acting upon the Transient Receptor Potential Vanilloid 1 (TRPV1) receptor has been found to have positive effects on swallowing. Black pepper oil aroma has been shown to increase the frequency of automatic swallowing and reduce the latency of swallowing [146] and ingestion of capsaicinoids and piperine reduced swallow latency and aspiration [147, 148]. In an RCT of patients with PSD, significant improvements in swallowing outcome measures were seen in the intervention group treated with oral capsaicin before meals for three weeks compared to the control group [149].

1.8.5 Central and peripheral neuro-stimulation

Neuro-stimulation of muscles involved in swallowing (peripheral stimulation) or of the brain areas that control swallowing (central stimulation) is an emerging field in dysphagia rehabilitation and shows promising results but further research regarding methods, dosing

and timing is needed [150]. Transcranial direct current stimulation has been shown to result in improved swallow function compared to sham in a good quality double blinded RCT [151]. In a meta-analysis, repetitive transcranial magnetic stimulation compared to sham stimulation resulted in significantly better outcomes in patients with PSD[152]. Both of these central neuro stimulation studies found improved results in stimulation over the non-affected hemisphere. Neither of these techniques are used in usual clinical practice at present. Pharyngeal electrical stimulation is a peripheral stimulation technique whereby a catheter with electrodes is placed in the pharynx and sensory stimulation is delivered aiming for functional reorganisation of the swallow pathways and has been shown to speed up weaning and improve secretion management in tracheostomised stroke patients.[153]. Although positive early trials found improvements in swallowing a large RCT in stroke patients was neutral [154]. Another peripheral neuro-muscular electrical stimulation (NMES) is being used clinically in the US but national guidance in the UK states that clinical use can only be carried out as part of a research/audit project due to the lack of good quality evidence [155]. A recent systematic review found 10 out of 11 studies (n=784) demonstrating that NMES +/- conventional therapy compared to conventional therapy or placebo resulted in significantly greater improvements in swallowing but due to heterogeneity of methodology a meta-analysis was not conducted [156].

1.8.6 Skill based training

As with other areas of stroke rehabilitation there is a recent acknowledgement that task specific skill training is key in effective swallowing therapy. Peripheral weakness in swallow musculature is unlikely to be present initially post stroke. Central cortical and or brainstem damage or interrupted pathways to oral and pharyngeal cavities are the predominant cause

of the dysphagia and can impact on swallow strength and skill [157]. Thus isometric strengthening exercises alone have been criticised for not addressing the physiological and biomechanical impairment in post stroke dysphagia [158]. The concept of swallow skill training is a recent development in dysphagia therapy and focusses on acquisition or refinement of the skill of swallowing by graded practice. Several of the traditional therapeutic techniques use swallowing as the exercise such as Masako, effortful swallow and Mendelsohn and thus could be considered task specific skill training but also maintain an element of strength training. The McNeil Dysphagia Therapy Program (MDTP) also uses swallowing as the task to improve the strength, speed and coordination of swallowing in patients with pharyngeal dysphagia. It involves 15 sessions over three weeks, practicing effortful or 'hard' swallows and progresses through saliva swallows to swallowing boluses of increasing size and texture. By doing so it follows the principles of maximising the opportunity for neuroplasticity; intensive, repetitive, salient, task specific and progressively challenging. A recent RCT found greater improvements in swallow function and physiology in patients receiving MDTP compared to usual care [159]. Instrumental assessment is required prior to initiation of the intervention to identify which viscosity and volume of bolus to begin the therapy [160]. Therapy is also very intensive with only MDTP trained SLTs able to deliver the intervention and whether this level of intervention is feasible in acute or rehab settings is unclear.

1.8.7 Biofeedback in dysphagia

Motor patterns for the pharyngeal swallow are modulated by the sensory information received about the bolus before it is transferred to the pharynx – feedforward control [161]. The pharyngeal swallow can also adapt to changes in the structure of the oropharyngeal or laryngeal cavities or based on feedback control [162]. Healthy adults can alter their

pharyngeal swallow using visual feedback about pharyngeal pressure using manometry [18], strength/amplitude of their swallow using surface electromyography (sEMG) [163] and laryngeal closure using videofluoroscopy [164]. Using biofeedback in swallowing therapy is not new but neither is it used widely in clinical practice [165]. Nor is there national recognition and guidance regarding its use. No such systematic review has been published looking at biofeedback in dysphagia therapy. Bogaardt presented a systematic review into sEMG as a biofeedback tool at a conference in 2009 in which it was reported that 33 out of 47 tube fed patients across the trials returned to an oral diet after treatment [166]. Although this appears promising none of the studies were randomised controlled trials (RCTs) and no full text publication was available to determine the quality of the studies and understand what the treatments involved. Other biofeedback tools are available which can be paired with a range of different swallowing strength and skill therapies. Such a review is necessary to bring together the research in this field, evaluate the evidence for its use in clinical practice, define the most effective treatment protocols and determine the priorities for further research.

1.9 Summary and aims of the research

Post stroke dysphagia is common and can result in negative health consequences. Early detection is important therefore screening tools need to be highly accurate in identifying dysphagia and those at risk of aspiration. Nurses usually carry out dysphagia screening but these basic water swallow tests often over diagnose dysphagia leaving patients NBM until further assessment. They can also miss silent aspiration which may lead to pneumonia. Patients are commenced on normal diet textures when they have only been assessed with water. Despite being safely able to swallow water, patients may have difficulties chewing, manipulating or clearing solid textures from the oral cavity. Whilst this may not pose

immediate risks of aspiration, dysphagia with diet textures may lead to malnutrition or choking. There is evidence that more comprehensive screening tests can address some of these concerns and allow nurses to make early dietary recommendations. However, little is known about how the accuracy, practicability, clinical utility and cost effectiveness compares between the tests already published.

The DTNAx appears more comprehensive than the other tools discussed in the introduction, but no systematic review of the literature exists to explore if other tools may be superior. The first aim of this thesis was to:

Systematically review the literature to describe and compare the diagnostic accuracy, clinical utility and cost effectiveness of the comprehensive screening tests available and perform a quantitative meta-analysis with accuracy data to discover the most suitable tool.

The DTNAx tool has not however, been validated therefore it is unclear whether the tool is accurate in identifying dysphagia and aspiration in acute stroke and results in safe and appropriate dietary recommendations by DTNs. The second aim of this thesis was to:

Perform a clinical trial to assess DTNAx for diagnostic accuracy and reliability.

Nurses are key in screening for dysphagia, and becoming a DTN is an extended nurse role in the acute stroke pathway. This involves training and an assessment of their competency to be DTNs. Once signed off they (as part of a team of DTNs) are expected to perform DTNAx on all patients admitted to the unit. If they are not carried out as intended this may impact on their ability to identify dysphagia or unsafe swallowing recommendations may be made, it is unclear whether nurses value the role and are committed to performing the assessments as intended. Therefore, the third aim of this thesis was to:

Explore the role of the DTN in acute stroke from the perspective of the users through semi-structured interviews

Diet and fluid modification is a short-term approach to compensate for dysphagia in order to maintain oral intake. Ongoing dysphagia and living with modifications such as thickened fluids or swallow strategies can impact on oral intake and quality of life. Therefore, dysphagia rehabilitation that reduces impairment and improves swallow function is essential. The evidence base for dysphagia rehabilitation is growing and the quality of the research is improving but there are still many questions remaining regarding which treatment is superior for which patient, at what dose and when in their pathway post stroke. Both traditional strength training and task specific skill training have a strong theoretical underpinning and biofeedback helps to give feedback on performance and a level of challenge that is required to maximise their potential. It is unclear which method of biofeedback or exercise at what dose gives better outcomes for patients.

From the literature, sEMG appears to be the most commonly studied form of biofeedback but as no such review has been completed to explore it and other forms of biofeedback, the fourth aim of this thesis was to:

Complete a systematic review and meta-analysis of biofeedback as an adjunct to dysphagia therapy to discover the most suitable protocol giving the best patient outcomes.

Very little dysphagia rehabilitation research has been conducted with acute stroke patients, but this may be most opportune moment to deliver intervention. Neuroplastic changes occur more in the first few month's post stroke and whilst patients are in hospital, delivering intensive therapy would be much more practical. Little is known about the feasibility of delivering an intensive dysphagia intervention of this kind at this stage of their pathway.

Therefore, using the protocol identified in the systematic review the final aim of this thesis was to:

Conduct a feasibility randomised controlled trial of biofeedback as an adjunct to dysphagia therapy in acute stroke.

Chapter 2: Systematic review and meta-analysis of comprehensive swallow screening tests

The data from this chapter has been published:

- Benfield JK, Everton LF, Bath PM, England TJ. 2020 Accuracy and clinical utility of comprehensive screening assessments in acute stroke: A systematic review and meta-analysis. Journal of Clinical Nursing. 29 (1).

Contributions:

The author performed the searches, carried out data extraction, analyses and wrote the manuscript. Lisa Everton reviewed the data extraction and decisions for inclusion for any inaccuracies and reviewed the manuscript.

2.1 Introduction

There are a multitude of non-swallow and water swallow screening tools described in the literature and systematic reviews have demonstrated that some of the best tools have good sensitivity but often lower specificity [88]. This translates to many patients unnecessarily remaining nil by mouth (NBM) for prolonged periods, with or without nasogastric tube feeding, until they are assessed by a SLT, which can have negative consequences [97, 98]. Water swallow tests have been criticised because swallowing water is not the same as swallowing food [167] and the tools have often been validated for screening aspiration, one of the possible consequences of dysphagia, rather than for the presence of dysphagia itself [168]. Reduced efficiency or uncontrolled oral and pharyngeal transit and clearance, impaired mastication and reduced sensation may result in other symptoms such as choking and sub-optimal nutrition [26, 32]. Aside from water swallow tests, there are several more comprehensive swallowing tests that mean non-specialists can screen for dysphagia and also assess various diet and fluid consistencies, so safe oral intake may be commenced earlier. To date there has been no review identifying, describing or comparing these more comprehensive tests.

It is essential that dysphagia screening tools have adequate accuracy and are safe to use clinically. The UK National Institute of Health and Care Excellence (NICE) 2016 Stroke Guidelines say that swallowing should be assessed using a validated tool [41]. There is also a move to demonstrate the clinical utility of screening and diagnostic tests, not only the technical performance in accurately screening for and diagnosing a condition [169, 170]. In the case of patients with dysphagia, clinical utility refers to how the tests improve the clinical

outcomes of the patients such as pneumonia rates and be more cost effective than other tools or pathways.

2.2 Aims

A systematic review was conducted to describe the comprehensive tools that are available for nurses or other members of the multidisciplinary team (MDT) to screen swallowing and assess for safe oral intake post stroke. The clinical utility of the tests is described, the results of a meta-analysis are presented and the quality of the tools that had undergone validation is discussed.

2.3 Methods

A systematic review of the literature was completed by searching databases; MEDLINE, EMBASE, CINAHL, Web of Science, Trial databases; Clinicaltrials.gov, ICTRP and grey literature from start to October 2018. Searches were carried out in English, see Table 2.1 for an example of the search criteria used in EMBASE. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses [171] guidance was followed (Appendix 2). Identified studies at different stages of the process were managed in folders on EndNote.

Table 2-1 Search strategy used in EMBASE database for systematic review of comprehensive swallowing tests

Number	Searches
1	assessment.mp.
2	screen.mp.
3	stroke.mp. or cerebrovascular accident/
4	swallowing/
5	1 or 2
6	3 and 4 and 5

2.3.1 Inclusion criteria

Inclusion criteria for the narrative review was broad as the number of published tools was estimated to be small. Studies were included in the narrative review if they had sufficient information in English or Spanish to establish that they described a comprehensive nursing or MDT assessment of swallowing to screen for dysphagia in stroke patients. Spanish was included to maximise inclusion and due to the author being fluent in the language. Comprehensive assessment was defined as a screening test for dysphagia that included assessing more than one diet or fluid texture allowing for recommendations of modified diet and fluids where appropriate. For the quantitative analysis, studies were included if they gave data regarding the accuracy of the assessment tool such as sensitivity and specificity. Studies were also included that reported the cost effectiveness or clinical utility of a test.

2.3.2 Study selection

One reviewer (JB) searched the titles and abstracts and excluded non-relevant studies. Full text was requested for relevant studies that could be included in a narrative review and, in the case of validation studies, a quantitative review. Data extraction and assessment of quality were carried out by the same reviewer (JB). Decisions for inclusion and exclusion, based on eligibility criteria were discussed and agreed with a second reviewer (PhD student LE). The second reviewer (LE) also reviewed and agreed the data extraction and quality assessments. Any disagreements were discussed with a third reviewer (PhD supervisor TE).

2.3.3 Data extraction

Data were extracted using a predesigned form (Appendix 3) including information on the content of the tests, possible outcomes, who administers the test and what training they

require. For validation papers data were collected using the Revised Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) [172] on the index and gold standard reference test used, the time between assessments, whether blinding occurred for example (Appendix 4). Authors were contacted where details were unclear or data were not present.

2.3.4 Risk of Bias

Risk of bias and applicability of primary diagnostic accuracy studies were assessed using the four domains of the QUADAS-2 [172]. 1. Patient selection; were patients recruited consecutively? Were they representative of an acute stroke setting? 2. Index test; who carried out the index test (the test being validated)? Were they blinded to other tests? 3. Reference standard; was the gold standard an acceptable assessment to compare to? Were the assessors blinded to the results of the index text? 4. Flow and timing; what was the time between the index and reference test? Were all data (including missing data) reported? Prior to the quality assessment it was decided that to be classed as low concern for applicability to an acute stroke population, over 50% of participants in the sample needed to be representative of acute stroke patients; defined as newly admitted (less than one week post stroke), including all types and severities of stroke and who may or may not have dysphagia. Overall quality was summarised using the GRADE guidelines [173] with quality levels summarised in table 2.2

Table 2-2 Definition of GRADE quality levels

Quality level	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect
Moderate	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	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

2.3.5 Statistical Analysis

Diagnostic accuracy data for the studies validating an assessment tool were summarised. Sensitivity, specificity, positive and negative predictive values, inter and intra rater reliability were included where available as were the respective confidence intervals which gives an indication of consistency. Receiver operating characteristic (ROC) curves were also included when reported in the studies where relevant. ROC curves are often used to quantify diagnostic accuracy in tests that give a continuous or ordinal score or result and it represents the relationship between sensitivity and specificity. In this way they can determine the cut off score for giving the best accuracy of the test. Studies that reported a 2x2 table detailing numbers of true and false positives and negatives were included in a meta-analysis[174]. The data were analysed in STATA using a hierarchical model accounting for both within and between study heterogeneity. This gives a summary sensitivity and specificity. With sufficient data (four or greater studies) the STATA *metandi* command uses a hierarchical summary ROC (HSROC) model to construct a HSROC curve. With less than four studies the *xtmelogit* command uses a bivariate model to give summary estimates of sensitivity and specificity [174-176]. Heterogeneity is assumed and accounted for in the statistics described above but estimation of the I^2 statistic is not routinely used in diagnostic test accuracy reviews as it does

not account for positivity threshold effects. Instead data can be inspected to ensure the results of the observed studies lie close to the summary curve.

2.4 Results

Database searches identified 868 studies and grey literature searches found a further 48 studies. See PRISMA flow diagram (Fig. 2.1). After duplicates were removed and titles and abstracts were screened, 60 full texts were requested and reviewed. After exclusions, 20 met the criteria for the narrative review.

2.4.1 Identified tests

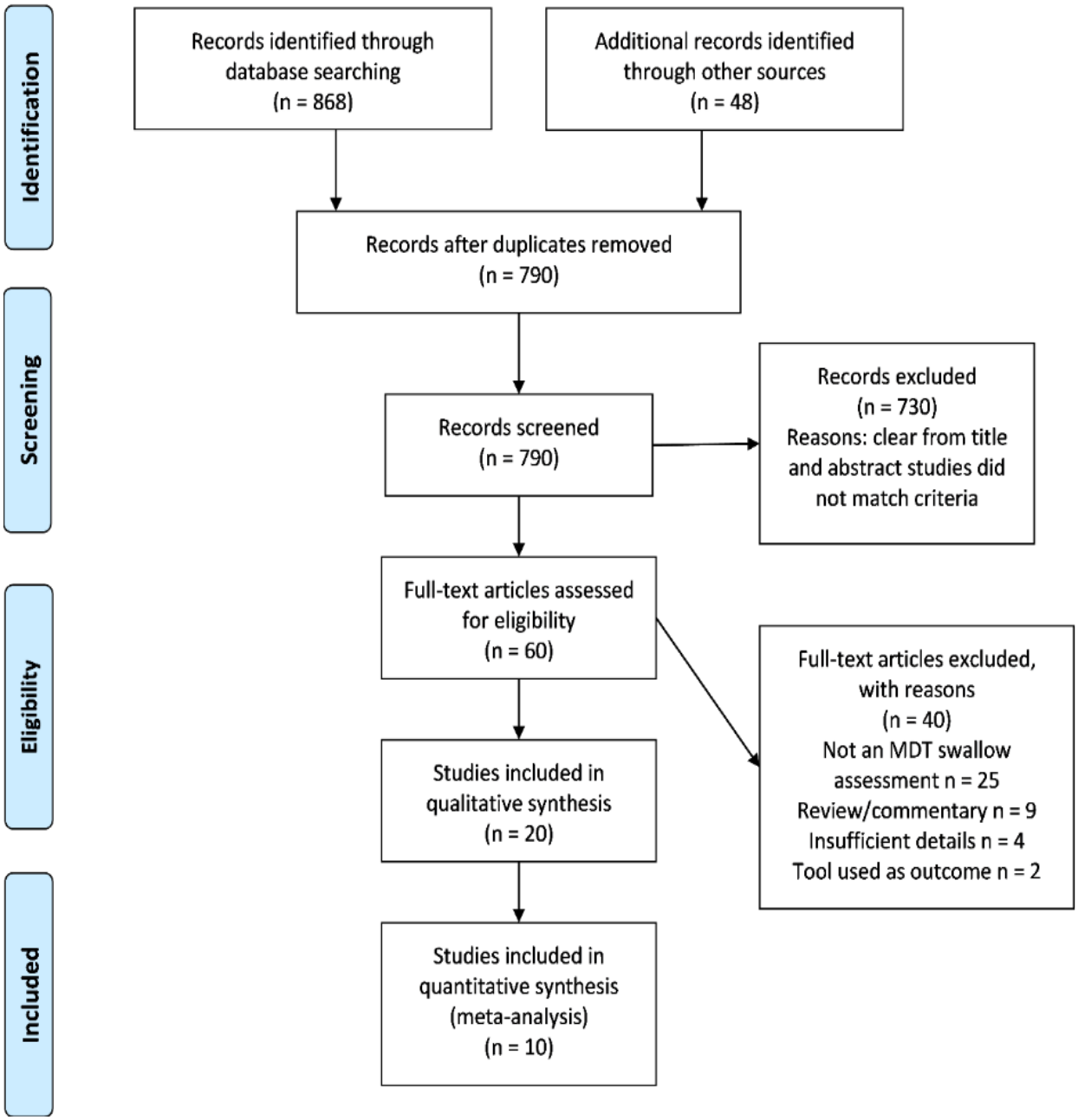
Five tests were identified and are summarised in Table 2.3. They are described as tests, screening tools and assessments. They all met the criteria as a screening tool for dysphagia and included testing different consistencies so that those who fail with water but can safely manage some oral intake can be recommended modified diet and fluids whilst they wait for further assessment by SLT. The Gugging Swallow Screening (GUSS, n=11 publications) and Volume Viscosity Swallowing Test (VVST, n=4) advise the use of instrumental assessments if dysphagia is identified on the test [177, 178]. The VVST and the Dysphagia Trained Nurse Assessment (DTNAx, n=3 publications) suggest they can also be used to review patient's swallowing [99, 179].

2.4.2 Non-swallow section

The GUSS, Bedside Swallow Screening Test (BESST, n=1) and DTNAx include a non-swallow section at the beginning before offering any oral trials [177, 180, 181]. This varies from observation of respiration, swallowing and alertness levels to direct testing of oromotor function. If this section is failed in the GUSS and the BESST then the rest of the assessment is

not administered and the patient remains NBM. In the DTNAx, whether the non-swallow section was passed or failed the assessment proceeds to swallow trials.

Figure 2-1 PRISMA flow diagram showing number of records identified, screened, eligible and included



The VVST and Two Volume Three Texture Test (2v/3t-P, n=1) do not include a non-swallow section and the papers are not clear about whether there are any patients who are not suitable to be tested [182, 183].

2.4.3 Oral trials

Many countries have not adopted the International Dysphagia Descriptors Standardisation Initiative (IDDSI) framework [125] and many of these tests were devised before IDDSI was launched in 2015. The DTNAx and the GUSS have been converted to the IDDSI framework [81, 177]. The oral trials will be described within in the IDDSI framework, levels (L) 1 to 7, where possible.

The tests vary in what is given orally. BESST evaluates two consistencies only, thin fluids (L0) and puree diet (L4). Whereas the GUSS trials thin fluids (L0), regular diet (L7) and a 'semi-solid' texture (L3). The 2v/3t-P tests different volumes (5 & 10mls) of thin fluids (L0), 'semisolid' (estimated L3 or L4) textures and regular diet (L7). The VVST tests different volumes (5, 10, 20mls) of thin fluids (L0), puree diet (L4) and nectar fluids (could be approximated to L2 fluids). The DTNAx is more comprehensive and tests a range of fluid volumes (5, 10, 100mls) and viscosities (L0, L2, and L3) and food textures (L4, L5, L6, L7). Several of the tests [177, 178, 183] comment on the order of the oral trials and argue that starting with thin fluids may result in aspiration and therefore they begin with puree diet (L4) or thickened fluids.

Table 2-3 Summary of the multidisciplinary comprehensive swallowing assessment tools used in acute stroke

Test	Studies identified	Test description	Test recommendations	Who can administer	Time of administration	Training required
Bedside Swallow Screening Tool (BESST)	Boaden 2011	Pre-screening & test with L0 and L4 consistencies.	3 options: 1. L0 fluids & L7 diet 2. L4 diet and fluids 3. NBM	Nurses	10 minutes	None
Dysphagia Trained Nurse Assessment DTNAx (Previously named 'Screening for dysphagia')	Heritage 2001, Heritage 2003 & Benfield 2018	Pre-screening checklist, Oromotor test, test of thin fluids progressing to level 2 & 3 fluids if unsafe and test L4, L5, L6, L7 diet as safe.	13 options: 1. L0 fluids & L7 diet 2. Any combination of L0, L2 or L3 fluids and L4, L5, L6, L7 diet 3. NBM	Nurses	20 minutes	One day theory and practical. 4 x assessments completed independently then competency Ax with SLT
Gugging Swallow Screen (GUSS)	Trapl 2007, Merino 2014, John 2015, AbdelHamid 2017, Samia 2017, Palli 2017, Trapl 2017, Warneke 2017, Teuschl 2018, Ferreira 2018, Umay 2018	Preliminary indirect assessment – cough & swallow function. Direct assessment with 3-5 tsps (L3), 3, 5, 10, 20, 50 mls L0, 1.5cm piece of L7 diet x 5	4 options 1. L0 fluids & L7 diet 2. Level 1-2 fluids and L5 or L6 diet 3. L2-L3 fluids and L4 diet 4. NBM	Nurses & SLTs	5-10 minutes	10-15 minute theory, demonstration of GUSS by experienced nurse.
Volume Viscosity Swallowing Test (V-VST)	Rofes 2014, Clave 2008, Guillen-Sola 2013, Rofes 2018	Assess 5, 10, 20 mls ~L2 fluids, then 5, 10, 20mls thin fluids as safe, then 5, 10 & 20mls L4 diet. Observation of signs & pulse oximetry.	26 options: 1. L0 fluids and L4 diet 2. Any combination of 5, 10 or 20mls of L0 or ~L2 fluids and/or 5, 10 or 20mls of L4 diet 3. NBM Fluids administered via syringe	Nurses, Physicians, Dieticians and SLTs.	5-8 minutes	Specific V-VST courses including theory (description, validation, algorithm, clinical cases) and practice with real patients
2 Volume, 3 texture test (2v/3t-P)	Cocho 2015	5mls then 10mls of ~L3/L4. 5mls then 10mls of L0 Then 1.5 cm piece L7 diet Observation of signs & pulse oximetry.	Unclear but likely 6 options: 1. 5 or 10mls L0 fluids & L7 diet 2. Any combination of 5 or 10mls L0 and 5 or 10mls of L3/4 or L7 diet 3. NBM	Nurses	No details	No details

International Dysphagia Diet Standardisation Initiative (IDDSI) Levels (L) are used. ~ is used to denote when the level is an estimation from another descriptor classification.

Justification for the inclusion of different textures was a theme that emerged from the literature. Umay et al 2018 points out that water is not the only thing that patients swallow thereby only testing water may result in false positives [184]. Boaden 2011 argues that a sufficient quantity of thin fluids needs to be included in the test because small amounts of water are not representative of normal swallowing [180]. Ferreira et al 2018 suggests that assessing different consistencies is more representative of normal eating habits [185]. John et al 2015 describe how the GUSS has replaced a water swallow test in one stroke centre because the team were concerned about the safety of starting patients on diet after just being tested with water [186].

2.4.4 Criteria for detecting aspiration or dysphagia

Most of the tests use clinical judgements to determine presence of aspiration or dysphagia. In particular, all tests use presence of cough and voice changes and most use lack of laryngeal elevation [81, 177, 180, 183]. In addition, the VVST and 2v/3t-P use a drop in oxygen saturations of >2% to detect silent aspiration. Other criteria varied between tests, see Table 2.4 for details of the full criteria each test uses to determine aspiration or dysphagia.

Table 2-4 Criteria for detecting aspiration and/or dysphagia on each of the comprehensive swallowing tests.

Test	Oral residue	Drooling	Ability to chew	No laryngeal elevation	Reduced laryngeal elevation	Delayed swallow	Voice change	Breath change	Cough post swallow	Throat clear	Multiple swallows	Reported pharyngeal residue	Drop O2 sats >2%
GUSS		✓		✓		✓	✓		✓				
DTNAx	✓		✓	✓		✓	✓	✓	✓				
BESST				✓	✓		✓	✓	✓	✓	✓		
2v/3t-P	✓	✓		✓			✓	✓	✓				✓
VVST	✓	✓					✓		✓		✓	✓	✓

GUSS – Gugging Swallow Screen, DTNAx – Dysphagia Trained Nurse Assessment, BESST – Bedside Swallow Screening Test, 2v/3t-P – 2 Volume, 3 Texture Pulse oximetry Test, VVST – Volume Viscosity Swallow Test.

2.4.5 Outcomes

A common theme was highlighted in the literature; non-expert professionals can use the tests to commence patients on safe oral intake who would otherwise remain NBM from failing a water swallow test [99, 177, 179, 180, 183, 186].

The outcome of the tests can be: 1. Pass - where normal diet and fluids are recommended, 2. Fail – where the patient is recommended to remain NBM or 3. Fail - with recommendations of a modified diet and fluids. The more comprehensive the test the wider the range of modified diet and fluid recommendations. The BESST only recommends puree/pudding (L4) consistency as the modified option. The VVST and 2v/3t-P can recommend different volumes of thin fluids (L0), thickened fluid and pureed diet (L4). The DTNAx can recommend several different thickened fluids and a range of modified diets. Several tests recommend textures that have not been directly tested; the BESST and VVST allow recommendations of normal diet (L7) when only puree texture is assessed and the GUSS recommends 'soft food' and different levels of thickened fluids when only thin (L0), puree/pudding (L4) and normal diet (L7) are tested.

None of the studies validating the tools collected outcomes of the patients following the initial index and reference tests.

2.4.6 Administration time

The GUSS, VVST, BESST are reported to take between 5-10 minutes to administer, the DTNAx takes around 20 minutes and there is no information on the 2v/3t-P test.

2.4.7 Pathway

Three of the tests [81, 180, 183] have been designed and, in some cases [180], validated to be the initial swallow test an acute stroke patient receives before commencing oral intake. The other two [177, 182] are intended to be used after an initial screening to identify those at risk of dysphagia who need a more detailed test.

2.4.8 Profession, training and competence

The tests are designed to be carried out by non-specialists in dysphagia, in most cases nurses [99, 177, 180, 183] but also physicians and dietitians [182]. The GUSS and the VVST papers suggest it can also be used by SLTs as a standardised bedside assessment [182, 185].

Little is known about the training required in order to be able to administer the tests, from what has been documented the training received is very variable. The BESST requires no training. The GUSS required a short theory session and an observation of the test being administered. The VVST and DTNAx require theory and practical sessions using the test. The DTNAx includes an assessment of competency in administering the test by an SLT.

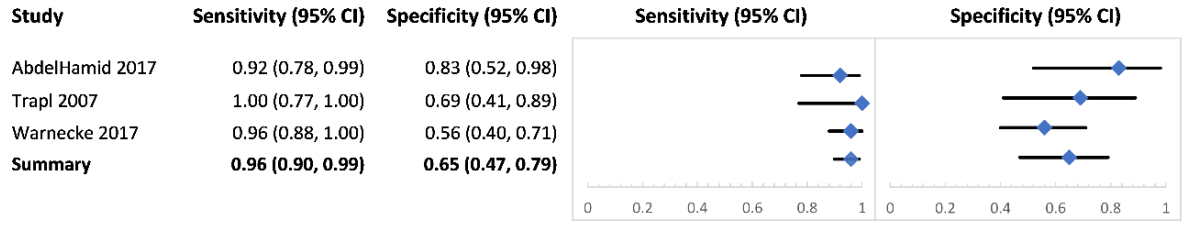
2.4.9 Accuracy

Three of the identified tools [177, 178, 180] have undergone validity and reliability testing (Table 2.5) and the DTNAx was being validated – (Clinical trials.gov NCT03700853). The GUSS and the VVST used an instrumental assessment (FEES or VFS) as the gold standard to validate the tests, the BESST was validated against an experienced SLT performing a clinical bedside assessment. All tests demonstrated good sensitivity (87.5% - 100%) and variable specificity (28% - 96.1%). The lower levels of specificity came from the VVST for identifying aspiration

[178, 179, 182] but sensitivity (94%, 95% confidence interval, CI, 0.87–0.98) and specificity (88%, 95% CI, 0.50–0.99) for identifying dysphagia was higher [182].

Only three of the studies [177, 187, 188], all validating GUSS, reported detailed data that could be included in a meta-analysis. Figure 2.2 compares validation data across these studies; overall, pooled GUSS sensitivity and specificity was 0.96 (CI 95% 0.90 - 0.99) and 0.65 (CI 95% 0.47 - 0.79) respectively. The HSROC curve could not be estimated due to there being less than four studies and thus heterogeneity between studies could not be commented on.

Figure 2-2 Forest plot comparing and pooling the sensitivity and specificity of the three studies validating the Gugging Swallow Screening test (GUSS)



CI = Confidence Intervals.

2.4.10 Quality

Most studies demonstrated very low [178, 179, 182, 184, 185, 187-189] or low quality [177] according to the QUADAS-2 [172] and GRADE criteria [173]. Table 2.6 shows the risk of bias and concern for applicability of each test along with the level of quality. Reduced quality was due to concern or uncertainty regarding risk of bias or applicability of index test, reference test, patient selection methods or flow and timing. The study validating BESST [180] demonstrated good study design, accuracy and reliability but was scored as moderate quality

due to lack of a gold standard reference test and imprecise results with wide confidence intervals.

2.4.11 Clinical utility and cost effectiveness

No studies evaluating the cost effectiveness of these tools over other tools or pathways were found. However, several studies evaluated the effect of using these more comprehensive tests on the clinical outcomes of patients.

In a retrospective study (N=384) [190], the GUSS test was introduced into a stroke service during out of hours periods where no SLTs were available to assess and manage swallowing. This resulted in significantly reduced pneumonia rates from 11.6% before the introduction to 3.8% after (p=0.004). Median length of hospital stay also decreased from nine days to eight days (p=0.033). However, in another retrospective database study (N=1394) [191] there were no differences in pneumonia rates between patients admitted with a stroke and assessed with GUSS (5.0%) and those not assessed (5.5%). Due its methodological design, groups were not matched therefore limited conclusions can be drawn. The 2v/3t-P test also resulted in a significant reduction in pneumonia rates (6.2% before vs. 2.1% after, p = 0.05) in a prospective analysis of consecutively admitted patients (N=418) to the stroke unit when it replaced a water swallow test [183]. A published clinical audit (N=61) described how acute patients were seen quicker and the number of days they spent NBM dropped by over 30% following a fivefold increase in the number of nurses trained to perform the DTNAx [81].

Table 2-5 Diagnostic accuracy of multidisciplinary dysphagia assessments that have undergone validation.

Test	Study	N	Reference test?	Validated for?	Sensitivity % (and CI if reported)	Specificity % (and CI if reported)	PPV % (and CI if reported)	NPV % (and CI if reported)	ROC (and CI if reported)	Inter-rater reliability (and CI if reported)
Bedside Swallow Screening Test (BESST)	Boden 2011	136	SLT bedside assessment	Dysphagia	From 87.5 (76.0-99.0) to 92.9 (85.1-100)	From 70.1 (59.9 -80.4) to 81.6 (72.9 -90.3)	From 62.9 (50.9-74.9) to 71.4 (58.8-84.1)	From 92.3 (58.8-84.1) to 94.7 (88.9-100)	Not reported	81% agreement Kw=0.61 (0.45-0.77)
Volume - Viscosity Swallowing Test (V-VST)	Clave 2008	85	VFS	Aspiration	100	28.8	28.8	100	Not reported	Not assessed
	Guillen-Sola 2013	52	VFS	Aspiration	88.2	71.4	60	92.6	Not reported	Not assessed
	Rofes 2014	134	VFS	Aspiration	91 (0.78–0.99)	28 (0.17–0.34)	21	94	Not reported	k=0.628 (0.45–0.78)
				Dysphagia	94 (0.87–0.98)	88 (0.50–0.99)	98	70		
Gugging Swallow Screen (GUSS)	Trapl 2007	50	FEES	Aspiration	100	50-69	74-81	100	Group 1: 0.77 (0.53- 1.02) Group 2: 0.93 (0.83 - 1.03)	k =0.835, *P*<0.001
	Abdelhamed 2017	42	FEES	Aspiration	93.3	83.3	93.3	83.3	0.94 (0.85–1)	k=0.84, P>0.05, PO=91%
	Warneke 2017	100	FEES	Aspiration	96.5 (87.8–99.5)	55.8 (39.8–70.9)	74.3 (62.8–83.7)	92.3 (74.6–98.9)	0.76 (0.67–0.84)	Not assessed
				Dysphagia	98.5 (92.3–99.6)	53.3 (34.3–71.6)	83.1 (73.3–90.4)	94.1 (71.3–99.8)	0.76 (0.66–0.84)	

Test	Study	N	Reference test?	Validated for?	Sensitivity % (and CI if reported)	Specificity % (and CI if reported)	PPV % (and CI if reported)	NPV % (and CI if reported)	ROC (and CI if reported)	Inter-rater reliability (and CI if reported)
Gugging Swallow Screen (GUSS)	Samia 2017	40	FEES	Aspiration	93.8	96.1	96.2	93.7	Not reported	Not assessed
	Ferriera 2018	174	GUSS	GUSS score	100	43	not reported – no data to calculate	not reported – no data to calculate	Nurse 1 = 0.987 Nurse 2 = 0.991	k= 0.818 – 0.905 with p<0.001
	Umay 2018	113	FEES	Aspiration	95.3-97.5	75.2-76.2	84.3	95.1-95.3	0.885-0.913	ICC = 0.955 (0.935-0.969) p< 0.001
				Dysphagia	95.3-97.5	69.6-72.2	73.6-78.4	80.0-81.3	0.791–0.822	
Dysphagia Trained Nurse Assessment (DTNAx)				Undergoing Validation – ClinicalTrials.gov Identifier: NCT03700853						
2 Volume,3 texture test (2v/3t-P)				No validation studies found						

CI =95% Confidence Interval, k= Kappa, kw = Weighted Kappa, ICC = Intra-class Correlation Coefficient, PPV = Positive predictive value, NPV = negative predictive value. ROC = Region under the Curve. The shaded areas indicated the studies that met the criteria for inclusion in meta-analysis.

Table 2-6 QUADAS-2 scores for risk of bias and concern for applicability of the diagnostic accuracy of the studies included in the systematic review multidisciplinary swallowing assessments.

Assessment	Study	Patient selection		Index test		Reference standard		Flow and timing	Overall quality of evidence based on GRADE criteria
		Risk of bias	Concern for applicability	Risk of bias	Concern for applicability	Risk of bias	Concern for applicability	Risk of bias	
Bedside Swallow Screening Test (BESST)	Boaden 2011	Low	Low	Low	Low	Low	Low	Low	**Moderate †%**
Volume -Viscosity Swallowing Test (V-VST)	Clave 2008	High	High	Low	Unclear	Low	Low	Unclear	**Very Low **†‡¥**
	Guillen-Sola 2013	High	High	Unclear	Unclear	Unclear	Low	High	**Very Low **‡%†**
	Rofes 2014	High	High	Low	Unclear	Low	Low	Low	**Very low **†‡**
Gugging Swallow Screen (GUSS)	Trapl 2007	High	High	Low	Low	Low	Low	Low	**Low **†**
	Abdelhamed 2015	High	High	Low	High	Low	Low	Unclear	**Very low **‡¥†**
	Warneke 2017	High	High	Low	High	Low	Low	Low	**Very low **‡†**
	Samia 2017	Unclear	Unclear	Unclear	Unclear	Unclear	Low	Unclear	**Very low **‡¥†%**
	Ferriera 2018	Unclear	High	Unclear	Low	High	Low	Unclear	**Very low **‡%¥†**
	Umay 2018	High	High	Unclear	Unclear	Unclear	Low	Low	**Very low**‡% †**
Dysphagia Trained Nurse Assessment (DTNAx)		Undergoing Validation – ClinicalTrials.gov Identifier: NCT03700853							
2 Volume,3 texture test (2v/3t-P)		No validation studies found							

GRADE rating downgraded due to: **%**concern or uncertainty regarding risk of bias or applicability of reference test **†**imprecise results *****concern or uncertainly regarding risk of bias or applicability of patient selection methods **‡**concern or uncertainty regarding risk of bias and/or applicability of the index test **¥**risk of bias in flow and or timing

2.5 Discussion

Nurses and other non-specialists in dysphagia assess swallowing and recommend diet and fluid intake in post stroke patients. Little is known about the content, accuracy or the way these assessments are carried out. It is important that the tools used during these assessments have undergone validation to ensure they are accurate in identifying dysphagia and that patients are being recommended safe oral intake to prevent complications such as aspiration pneumonia, choking or undernourishment.

A systematic review was conducted to identify and describe the available tools and compare their accuracy and clinical utility where this had been tested. Five different tests were identified from the literature. The tests differed in content, the recommendations generated, the professionals administering the test and the training and competency requirements. Only three of the tests have been validated against a gold standard swallowing assessment. There was no single test that was highly accurate, backed up with a high-quality study design and that demonstrated clinical utility.

The GUSS has undergone the most validation testing of all the tests and was the only test in the studies identified that was eligible for the meta-analysis. Overall, it demonstrated good sensitivity (96%) and lower specificity (65%). These pooled results represent the overall ability of the GUSS to identify risk of aspiration rather than dysphagia as not all of the studies validated the test for identification of dysphagia [177, 188]. It is possible therefore that some of the patients who pass the test in fact have dysphagia and are at risk of choking or undernutrition. The VVST had the highest accuracy for identification of dysphagia [182].

The accuracy results for the meta-analysis must be interpreted cautiously due to the limited number of studies and the mostly poor or very poor quality or applicability. Two of the studies

selected patients who were already suspected as having dysphagia [177, 188] and one excluded mild strokes [187] therefore they did not represent the broad range of the acute stroke population in whom the test may be used. In two of the studies [187, 188] the GUSS was performed by experts rather than non-specialists which is not applicable to the clinical use of the test. In one of the studies[188] the timing was unclear between the GUSS and the reference test (FEES) and there was no reporting of any missing data. Individually and to some extent in the pooled data the studies demonstrated imprecise results with wide confidence intervals especially with specificity. The issues with quality could have skewed the results; for example, the high sensitivity may in part be due to the test only being carried out on participants already identified as being at risk of dysphagia [177, 188] or with more severe strokes [187]. The strict non-swallow section which results in a test failure for those with reduced oromotor function and places the patient NBM until further assessment might explain the low specificity [187, 192]. This specificity is comparable to some of the best water swallow tests [193]. From a clinical utility perspective the GUSS may be better than no test [190] but not better than a water swallow test [191] at reducing pneumonia rates. There is also a jump between the diet and fluid consistencies tested to those recommended; for example, a patient can be recommended IDDSI L1 or L2 fluids and L5 diet without having been tested with any of these. In the same way, water swallow tests are also criticised for allowing normal diet intake without assessment [167]. Given it may not be any more accurate, safe or clinically effective than water swallow tests, and training and administration time is greater, the GUSS may be less cost effective.

The BESST was of moderate quality and had acceptable sensitivity and negative predictive value with lower specificity to identifying dysphagia. However, the reference test used was a clinical bedside assessment (CBA) which could be argued is not a gold standard assessment

of swallowing, especially because a validated CBA was not used. CBAs have been shown to be less effective at describing dysphagia and identifying aspiration [194] than gold standard instrumental assessments and the author acknowledges this as a limitation with the BESST validation.

The construct validity of the tests has not been reported. This pertains to how well a test is constructed to identify dysphagia based on what is known about dysphagia. There are some common characteristics across the tests that suggests good construct validity: all of the tests evaluate liquids and solids; and they all have criteria for judging both the oral stage and pharyngeal stages of swallowing. This includes specifics on identifying signs of aspiration such as cough and voice change which have been shown to be the most reliable signs in water swallow tests [95]. Progressive volumes of thin fluids also increases accuracy of identifying aspiration [95], most of the tests do this to some degree. However, there are limitations in some of the tests that reduce their construct validity. Two of the tests do not include food textures that are part of regular diet [178, 180]. The VVST administers fluids via a syringe which was also how the fluids were administered in VFS. This is not consistent with natural drinking and it is unclear whether safety and efficacy judgements made on the basis of syringe swallowing would still apply to natural drinking. Furthermore, it has been established that bedside assessments are limited in detecting silent aspiration[195]. Two of the tests have tried to address this by including pulse oximetry to measure a drop in oxygen saturation, however more recently this measure has been found not to be reliable in detecting aspiration[115]. These tests are designed to identify dysphagia with aspiration being one aspect of that and silent aspirators may present with other signs of dysphagia [196]. This may limit the potential of any bedside test to attain high accuracy scores for identification of

aspiration as to date there is no non-instrumental test that has been found to identify aspiration reliably.

Both the VVST and the GUSS follow on from a preliminary screening component to identify those who may be at risk of aspiration or dysphagia. The whole pathway (preliminary screen and test) has not been validated with consecutively admitted acute stroke patients for either of these tests. Perhaps this could be a more cost-effective pathway if both preliminary screening and then dysphagia testing are shown to be acceptable in diagnostic accuracy in methodologically robust studies.

Heritage 2003 argues that to manage dysphagia effectively SLTs need to share their skills, responsibility and workload with nurses [99]. Several publications suggested screening tests were not designed to replace the role of the SLT (23). Instead, they were meant as easy-to-follow tools for those best placed (30) with the best skills (21) to identify patients with dysphagia so that SLT resources could be better directed to assessment and management of those most in need (20). The Interprofessional Dysphagia Framework (IDF) sets out how non-SLTs can develop skills in dysphagia assessment and management at different levels [86]. The Foundation Level of training allows those competent to carry out a protocol-guided swallowing assessment for which training and competency verification is required. The level of training required is set at a high standard because these tests involve making clinical judgements on signs of dysphagia and aspiration that may be subtle. In the UK, SLTs develop these skills by completing at least an undergraduate module and post graduate training in the theory of dysphagia and must accumulate 40 hours of clinical experience to be competent to practice [197]. Training must therefore be essential if non-SLTs are assessing dysphagia. Whether training was required to use the tests identified in this review appeared variable and

the DTNAx is the only tool that has described a training and competency assessment that meets the IDF's criteria.

2.5.1 Limitations

This review only included studies published in English or Spanish, therefore published and non-published studies in other languages describing assessment tools may have been missed. There are likely to be many other nurse dysphagia assessments that have been developed by individual services that have not been published or described in the literature and therefore have not been included in this review. It is unlikely, however, that these in-house assessments have undergone rigorous validation without publication.

2.5.2 Future directions

To make decisions around which test is superior in diagnostic accuracy, further validation using robust study design is required. Information regarding clinical utility and cost effectiveness is also desirable to use with accuracy data to determine which tools should be used as standard in routine clinical practice. All the tests and gold standard comparators evaluate only small volumes of oral intake in order to make appropriate recommendations. However, little is known about how the recommendations are tolerated over time and whether there are any negative consequences such as pneumonia, choking incidents and malnutrition. Further studies should consider comparing tools using clinical outcomes at later time-points to ensure the tools are safe and effective. Future hyper-acute clinical trials may benefit from a robustly validated outcome tool that can be used by non-specialists to identify dysphagia [198].

2.5.3 Conclusions

There are several tools used by nurses and other non-specialists to screen for dysphagia and recommend oral intake for acute stroke patients with mild to moderate dysphagia. Three have been validated and show that they are good at identifying patients at risk of aspiration and dysphagia, but often over diagnose, resulting in patients unnecessarily being kept NBM or on modified oral intake. Overall, however, the quality of studies in this review was graded as poor or showing low applicability for use by non-specialists to assess for dysphagia within the acute stroke setting. There is limited variable quality evidence that these tests may reduce pneumonia, reduce length of time patients are NBM and awaiting a swallowing assessment compared to no test. Further validation is required with robust study design to discover the accuracy, clinical utility and cost effectiveness of these tests so that they can be evaluated and compared.

Chapter 3: The accuracy of the Dysphagia Trained Nurse Assessment in Acute Stroke

The data from this chapter has been published:

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Contributions:

The author collated, analysed and interpreted the data and wrote the chapter. Gwenllian Wilkinson analysed 10% of the videofluoroscopy files as a second reviewer for inter rater reliability analysis and reviewed the manuscript. The author presented the results nationally.

3.1 Introduction

The systematic review and meta-analysis found that only a handful of comprehensive screening tools have been published and fewer still have been validated with pooled accuracy close to that of water swallow tests[199]. The Gugging Swallow Screening[200], Volume Viscosity Swallowing Test[178] and Bedside Swallow Screening Test (BESST)[180] have been validated. Due to questions over methodological rigour, most studies were at high risk of bias and demonstrated low applicability to new stroke admissions[199]. Furthermore, there are concerns regarding safety that the outcome recommendations of these tests include several levels of modified diet and fluid that are not directly tested in the assessment[199].

The Dysphagia Trained Nurse Assessment (DTNAx) has not undergone validation, but addresses some of the major concerns regarding the other published comprehensive screening tests. The DTNAx includes an oromotor screen, but unlike other comprehensive screening tests, despite the outcome i.e. identification of oromotor impairment or not, it carries on to assess several trials of a range of diet and fluids consistencies. This is hypothesized to result in a higher specificity in the DTNAx compared to the other tests and could prevent many patients unnecessarily waiting NBM with or without nasogastric feeding until SLT assessment[201]. The DTNAx assesses a wider range of consistencies and volumes than the other tests. This allows a greater range of recommendations to be made by the assessors. The DTNAx only allows recommendations of the specific diet and fluid consistencies deemed safe and efficient on direct testing using the tool unlike all the other tests. Like the VVST the DTNAx required users to complete theory and practical training but in addition the DTNAx includes a competency assessment with the SLT to ensure that users are competent to use the tool, whereby adhering to the Interprofessional Dysphagia

Framework for Foundation Level competency. The DTNAx appears to be the most robust in terms of content but requires validation to ensure that is has good diagnostic accuracy. Therefore, the aim of this chapter was to validate the DTNAx tool against usual clinical SLT assessment (SLTAx) and gold standard VFS for identification of dysphagia and aspiration in acute stroke and to explore the accuracy of diet and fluid recommendations by DTNs using the tool.

3.2 Methods

3.2.1 Participants

New admissions to the Acute Stroke Unit at University Hospitals of Derby and Burton NHS Trust were screened prospectively and consecutively between January 2018 and March 2020. Participants were approached and recruited if they were over the age of 18 with a new clinical diagnosis of stroke (ischaemic or haemorrhagic). Participants were excluded if they had a history of dysphagia; a degenerative neurological condition or were medically unwell (as determined by the clinical care team). Initially, inability to attend VFS was an exclusion criteria, but this was amended as it skewed recruitment towards milder stroke patients. Participants were given written information pertaining to the study and provided written consent where able. Aphasia friendly patient information sheets were also available and often used to explain the study to those with communication or cognitive impairments (Appendix 5 & 6). The Stroke Persons Aphasia Group (SPIG) reviewed the information sheets and gave readability feedback which was used to improve them. Those who were unable to consent were also included to ensure full representation of stroke severity. In these cases, advice was sought from a personal or nominated consultee.

3.2.2 Study Protocol

The study was approved by the West Midlands - Coventry & Warwickshire Research Ethics Committee (REC ref: 17/WM/0209). It was registered on ClinicalTrials.gov (Identifier: NCT03700853) and the protocol and statistical analysis plan were published on Figshare prior to recruitment end [202]. The study has been reported using Standards for the Reporting of Diagnostic Accuracy Studies 2015 checklist [203] (Appendix 7).

3.2.3 Dysphagia Trained Nurse Assessment

All participants had their swallowing assessed as part of usual care using the DTNAx by one of 23 clinical Dysphagia Trained Nurses (DTN) on shift in the Acute Stroke Unit. The DTNAx (Appendix 1) is described in detail in Section 1.6.4.3.1. Dysphagia was defined by the presence of the defined safety or efficiency concerns on any of the sections of the assessment.

3.2.4 Speech and Language Therapy Assessment

The DTNAx was validated against usual SLTAx, obtained by a pool of 13 blinded SLTs from the acute hospital with experience in dysphagia ranging from one month to over 10 years. They obtained participants' medical history but not the outcome of the other swallowing tests. The assessments were not standardised but included an oromotor exam and assessment of oral trials. Dysphagia was defined clinically– those who had an impaired swallow that required modification, adaptation or strategies and ongoing SLT input. To reduce bias, signage behind the bed and any clues as to current oral intake recommendations were hidden. However, this could not be fully controlled if, for example, a nasogastric tube was in situ.

3.2.5 Videofluoroscopy

The DTNAx was validated against VFS, a 'gold standard' assessment for swallowing. However, there are certain technical and procedural variabilities that can make it less than gold standard. Using greater than 40% weight to volume of barium sulphate (Ba) has been found to leave a coating [204] and may be interpreted as residue, a consequence of pharyngeal stage impairment. There are challenges to achieving correct viscosities due to the inherent nature of Ba, but It is possible to achieve correct viscosities if systematic mixing protocols are used and are matched to measures of viscosity [205]. Recipes are also needed to standardise the concentration of contrast used to ensure adequate visibility on images without them leaving a coating in the oral or pharyngeal cavities [204].

Radiation safety must also be considered, different equipment set ups and screening protocols such as changing to pulsed fluoroscopy and using fewer pulses can reduce radiation dose, but this has a negative impact on quality of images. Analysing images at a lower pulse or frame rate changes the temporal resolution of the VFS [206] and reducing from 30fps to 15fps can result in less accurate interpretation [207, 208]. This is not surprising given that a swallow occurs in less than one second [77]. Bonilha and colleagues demonstrate that reducing the pulse rate is not necessary They showed that a VFS set to continuous screening at 30 frames per second using the MBSImP protocol, which takes an average of 2.9mins to administer, results in an average effective dose of 0.27 mSv [209]. Effective doses between 0.1-1 mSv are regarded as low dose [210], equal to 6-7 weeks of background radiation based on the UK average [211]. Specific documentation and sign off was required for ethics approval as this study involved radiation. In addition, the UK national diagnostic reference levels indicating the upper boundaries for screening time at 3.5 minutes. The Clinical Radiation

Expert and Medical Physics Expert at RDH signed off the Integrated Research Application System (IRAS) form with the following protocol:

The VFS was performed within 24 hours of the DTNAx. VFS were carried out by a blinded SLT, radiographer and/or radiologist. The data were acquired from continuous screening and recorded onto DVD at 25 frames per second using a Philips system. The oral trials were prepared using IDDSI [212] tested recipes containing 40% volume to volume barium sulphate solution concentration to ensure accuracy of VFS interpretation [204]. The assessment protocol (Table 3.1) was adapted from the Modified Barium Swallow Impairment Profile (MBSImP) [122] to be in line the oral trials received in the DTNAx and was expected to take three minutes.

Stopping criteria were included on the assessment form used by VFS clinicians to prevent participants from significant aspiration. This meant that for some participants not all boluses were administered due to safety concerns. Whereas VFS may be routine and beneficial for patients with dysphagia, an estimated 50% of participants with no dysphagia also underwent VFS. Ethics accepted this as it was argued that a number of patients with no dysphagia may be missed by the DTNAx and VFS would ensure that they were identified for ongoing management. It was essential to include those with no dysphagia in order to answer the research question and given dose was deemed by the medical physics expert as very low it was approved by the ethics committee.

Table 3-1. Videofluoroscopy assessment protocol

Videofluoroscopy ID _____ VERSION 1.3 May 2019

VIDEOFLUOROSCOPY RESEARCH PROTOCOL – Validation and Reliability testing of Dysphagia Trained Nurse Assessment

TRIAL	CONSISTENCY	AMOUNT	INSTRUCTION:	PAS >= 5, severe residue or unable to masticate GO TO … *	Tick if administered	Reason if not	Cough present Y/N
1	Thin Liquid (L0)	5ml via teaspoon	Clinician should administer the bolus and ask the patient to swallow	2			
2		5ml via teaspoon	Clinician should administer the bolus and ask the patient to swallow	3			
3		Single cup sip	"Take a sip as you normally would'. Self-administration is optimal from a white disposable cup (patient controls the amount but assist if needed)	5			
4		Sequential swallow (Remainder of cup approx. 80mls)	Instruction: "Drink the contents of this cup in your usual manner." Self-administration is optimal from a white cup, or but assist if needed.	5			
5	Mildly Thick Liquid (L2)	5ml via teaspoon	Clinician to administer	7			
6		Single cup sip	"Take a sip as you normally would'. Self-administration is optimal from a white disposable cup (patient controls the amount but assist if needed)	7			
7	Moderately Thick Liquid (L3)	5ml via teaspoon	Clinician to administer	9			
8		Single cup sip	"Take a sip as you normally would'. Self-administration is optimal from a white disposable cup (patient controls the amount but assist if needed)	9			
9	Puree (L4)	5ml via teaspoon	The clinician should administer the bolus.	STOP			
10	Minced and Moist (L5)	5ml via teaspoon	The clinician should administer the bolus.	STOP			
11	Soft and Bite sized (L6)	1 piece of cake (1.5cm³) coated with puree.	The clinician should administer the bolus and should instruct the patient to "chew this up and swallow".	STOP			
12	Normal/Regular (L7)	1 piece of biscuit (to fit inside the spoon) coated with puree.	The clinician should administer the bolus and should instruct the patient to "chew this up and swallow".	STOP			

*** Omit consistencies where safety concerns are evident and STOP Ax if necessary**

NB: Once complete – ensuring Videofluoroscopy ID has been completed at the top of the page – please fold and place in the box file

The MBSImP was used due to it being a standardised tool that has undergone reliability testing and which provides online training for users to learn to calibrate their scoring as per the tool's guidance. A systematic review concluded that there were no VFS analysis tools robustly validated with stroke patients [120]. Other comprehensive VFS tools assessing presence of dysphagia rather than consequences of dysphagia (aspiration/residue) in stroke were appraised but found to be inferior. For example, the Videofluoroscopy Dysphagia Scale (VDS) that in two retrospective studies of people with dysphagia was found to correlate with scores on other non-instrumental swallowing assessments and an overall cut off score was predictive of aspiration six months after stroke but the VDS has not been robustly validated for presence of dysphagia in stroke patients [213, 214].

Training was given to radiographers, radiologists and VFS SLTs regarding the assessment protocol and anonymisation practices prior to the commencement of the study, including specific instructions to ensure all the structures were in view and the whole swallow was captured (Appendix 8).

The VFSs were anonymised and later analysed by a blinded SLT (JB) trained in using the MBSImP. A second trained blinded SLT (GW) analysed 10% of the VFS to test inter-rater reliability. Aspiration was defined as a Penetration Aspiration Scale (PAS)[215] score of greater than 5. Dysphagia was defined by MBSImP cut off criteria (Table 3.2) that was derived from the MBSImP literature and training materials. A score of ≥ 1 is abnormal with the exception of: Components 1. lip closure, 5. Oral residue, 15. Tongue base retraction, 16. Pharyngeal residue where >= 2 is the cut off for abnormal [122, 216]. In the MBSImP training materials it is discussed that a later swallow onset alone does not constitute impairment. Furthermore, healthy adults with no dysphagia can trigger the swallow inferior to the

valleculae [217]. Hence in addition to the MBS classification for dysphagia/no dysphagia component 6 Initiation of Swallow was scored abnormal if ≥4. Despite having theoretically sound underpinnings these cut off scores have not been validated, nor is there normative data for age matched healthy adults available to distinguish dysphagia from normal swallowing.

Table 3-2. Modified Barium Swallow Impairment Profile (MBSImP) components and their cut of scores which define the presence of dysphagia

Component	Description	Cut off = dysphagia
1	Lip closure	≥2
2	Tongue Control	≥1
3	Bolus preparation/mastication	≥1
4	Bolus transport/lingual motion	≥1
5	Oral residue	≥2
6	Initiation of swallow	≥4
7	Soft palate elevation	≥1
8	Laryngeal elevation	≥1
9	Anterior hyoid excursion	≥1
10	Epiglottic movement	≥1
11	Laryngeal vestibular closure	≥1
12	Pharyngeal stripping wave	≥1
14	Pharyngoesophageal segment opening	≥1
15	Tongue base retraction	≥2
16	Pharyngeal residue	≥2

Safe and efficient fluids and diet consistencies were pre-defined by a combination of MBSImP criteria, PAS score and number of swallows (Table 3.3). PAS measures penetration and aspiration, a PAS score of 3 or greater implies reduced swallow safety and a PAS score of <3 is within normal limits [218, 219] therefore this was chosen as the cut off.

Multiple swallows indicate inefficiency in swallowing. Most boluses are swallowed in one with a second clearing swallow occurring in 20% of healthy adults [109, 220]. Therefore, for an efficient swallow the number of swallows should be <3.

Severe pharyngeal residue significantly increases risk of aspiration post swallow [221] and vallecular residue is associated with aspiration on subsequent swallows [222]. Residue signifies inefficiency in the swallow and can compromise nutritional status [223]. The MBS-ImP component 16 pharyngeal residue of ≥3 was used to measure severe residue.

Reduced mastication reduces the efficiency of swallowing. A score of >0 on MBS-ImP component 3 indicates an impairment in mastication or bolus preparation [122] therefore this was used as the cut off. Waito and Steele 2018 used PAS ≥3, number of swallows ≥ 3 and pharyngeal residue to define any impairment in safety or efficiency on VFS, although did not test solid textures. Therefore a mastication score was not used [224]. They used a more objective method of defining residue using the Normalised Residue Ratio Scale (NRRS) which uses NRRS valleculae >0.09 and NRRS pyriform >0.2 cut offs to define abnormal pharyngeal residue [222]. However, as the MBSImP components were already being evaluated in this study it was decided to use Component 16 score ≥ 3 for pharyngeal residue.

Table 3-3 VFS definition of a safe or efficient swallow used in deciding diet and fluid recommendations.

	Criteria for safe & efficient fluid	Criteria for safe & efficient diet
Least modified/restrictive	✓	✓
Safe: PAS < 3 on all trials of that consistency, pre, during or post swallow	✓	✓
Efficient: < 3 swallows per bolus	✓	✓
Efficient: Final MBSImP Component 16 Pharyngeal Residue Score < 3	✓	✓
Safe and Efficient: Timely and complete mastication MBSImP Component 3 = 0	n/a	✓

3.2.6 Reliability

To assess for intra and inter-rater reliability a second DTNAx was carried out by the same or a different DTN, respectively, blinded to the outcome of the other assessments.

3.2.7 Sample size

The planned sample size was rounded to 50 participants. For primary analyses, to achieve 90% sensitivity (95% CI 75%-100%) and a 60% specificity (95% CI 45%-75%) the sample size needed was 41.

3.2.8 Statistics

The findings were evaluated using IBM SPSS Statistics 26. Groups were compared using t-tests for continuous data, Mann–Whitney U for non-parametric continuous or ordinal data and chi-squared for categorical data. For determining diagnostic accuracy sensitivity, specificity, positive predictive and negative predictive values and their confidence intervals (CIs) were calculated. Inter and intra- rater reliability data were analysed using intra-class correlation coefficient for continuous data, kappa for dichotomised data and weighted kappa for ordinal data.

3.3 Results

Forty-seven participants were recruited (Table 3.4, baseline characteristics). Participants with and without dysphagia were equal with regards to age, sex, premorbid disability (mRS), occurrence of previous stroke and stroke type. The participants with dysphagia had a significantly more severe stroke, with an NIHSS 9.6 (6.5) vs 4.0 (3.9) compared to the participants with no dysphagia (p=0.001). Recruitment rate of participants with no clinical dysphagia was notably quicker than those with dysphagia, therefore to ensure a

representative sample[57], once 25 had been enrolled, recruitment continued with only those who had clinical dysphagia.

3.3.1 Timing of Assessments

Forty-seven participants undertook baseline DTNAx assessments, of which 46 had an SLTAx, 30 a VFS, 21 a repeat DTNAx by a different assessor and four had another DTNAx by the same assessor. Average time between the index DTNAx and SLTAx was 14.7 hours (SD 7.5) and VFS 15.5 hours (SD 6.3), the time between the second DTNAx by a different nurse was 19.6 hours (SD 6.6) (Table 3.5).

3.3.2 Dysphagia Severity

Dysphagia was defined by clinical SLTAx and was present in 22 (46.8%) of the participants with a median severity of 6 (IQR 4) on the 0-12 point Dysphagia Severity Rating Scale (DSRS)[225]. (Appendix 9). The scores ranged from 1-12 suggesting a broad range of dysphagia severities. A further 7 participants were identified by SLTs as having very mild dysphagia which did not require intervention, adaptation or modification, scoring 0 on the DSRS. Consistent across the recruitment period SLTs were blinded to the results of the other assessments in the majority of cases (69.6%).

Table 3-4. Baseline characteristics of participants

		Participants (n=47)	No dysphagia (n=25)	Dysphagia (n=22)	P
Age		73.0 (13.3)	71.5 (12.7)	74.8 (14.1)	0.410
Sex, female (%)		24 (51.1)	11 (44.0)	13 (59.1)	0.302
Premorbid mRS (/6)		0 (4)	0 (4)	0 (4)	0.897
Stroke type (%)	Haemorrhagic	4 (8.5)	1 (4.0)	3 (13.6)	
	Ischaemic or normal CT	43 (91.5)	24 (96.0)	19 (86.4)	0.237
Stroke Syndrome (%)	TACS	4 (8.5)	1 (4.0)	3 (13.6)	
	PACS	19 (40.4)	8 (32.0)	11 (50.0)	
	POCS	7 (14.9)	7 (28.0)	0 (0.0)	0.070
	LACS	14 (29.8)	7 (28.0)	7 (31.8)	
	Unconfirmed stroke	3 (6.4)	2 (8.0)	1 (4.5)	
NIHSS on admission (/42)		6.8 (6.0)	4.0 (3.9)	9.6 (6.5)	**0.001**
Time from stroke to recruitment (hours)		32.8 (22.5)	32.2 (20.5)	33.5 (25.0)	0.856
Previous stroke (%)		20 (42.6)	11 (44.0)	9 (40.9)	0.831

Data are number (%), median (interquartile range), or mean (SD). Dysphagia is defined by SLT (Dysphagia Severity Rating Scale[225] - DSRS >0) and excludes those with dysphagia not requiring SLT intervention or dietary modification (DSRS = 0). In the case of missing data (N=1) the VFS was used to determine presence of dysphagia.

Table 3-5 Number of participants that completed each assessment and mean time and standard deviation (SD) between assessments.

		Reference Assessments			
		DTNAx 2	DTNAx Repeat	SLTAx	VFS
Index Assessment: DTNAx1 (n=47)	Numbers	21	4	46	30
	Average time between assessments (hours)	19.6 (6.6)	11.5 (8.4)	14.7 (7.5)	15.5 (6.3)
All DTN assessments (n=72) including: DTNAx1 (n=47), DTNAx2 (n=21) DTNAx Repeat (n=4)	Numbers	n/a	n/a	70	47
	Average time between assessments (hours)	n/a	n/a	11.3 (8.3)	11.5 (7.7)

Data are number, or mean (SD).

3.3.3 Diagnostic accuracy for dysphagia

Of the 47 participants recruited, 46 had an index DTNAx and SLTAx, 24 of these had a further DTNAx by the same or a different nurse, this data were pooled to calculate diagnostic accuracy. For identification of dysphagia the sensitivity, specificity, positive predictor values (PPV) and negative predictor values (NPV) were 96.9% (95% CIs 83.8% to 99.9%), 89.5% (95% CIs 75.2% to 97.1%), 88.6% (95% CIs 75.4% to 95.2%) and 97.1% (95% CIs 83.1% to 99.6%) respectively. (Table 3.6).

Table 3-6 A 2x2 table comparing DTNAx index tests to usual clinical SLT assessment

Validation Clinical SLTAx (N=70)	SLTAx – Dysphagia	SLTAx – No dysphagia
DTNAx – Dysphagia	31	4
DTNAx – No dysphagia	1	34

	Value	95% CIs
Sensitivity	**96.9%**	83.8% to 99.9%
Specificity	**89.5%**	75.2% to 97.1%
PPV	**88.6%**	75.4% to 95.2%
NPV	**97.1%**	83.1% to 99.6%
Prevalence	**46.67%**	
Accuracy	**92.9%**	84.1% to 97.6%

DTNAx, Dysphagia Trained Nurse Assessment; SLTAx, Speech and Language Therapy Assessment; CIs, confidence intervals

DTNAx and VFS was carried out in 30 participants. Reasons for no VFS were not being able to sit out of bed (8/17), no VFS slot available (6/17), medically unwell (2/17) or technical problems (1/17). Of those that had a VFS a further 17 of these had another DTNAx by the same or different nurse therefore a total of 47 DTNAx results could be compared to VFS results. Using the original MBSImP cut offs as predefined in the protocol, *all* participants achieved the threshold for dysphagia on VFS. Given this was questionable, the data are presented for those with dysphagia requiring modifications to their diet or fluids as per the prespecified VFS criteria. For DTNAx identification of dysphagia compared to the VFS sensitivity, specificity, PPV, NPV and 95% confidence intervals were 45.7% (28.8% to 63.4%),

83.3% (51.6% to 97.9%), 88.9% (68.2% to 96.8%), 34.5% (26.17% to 43.87%) respectively. (Table 3.7).

In further exploratory analyses, SLTAx had sensitivity, specificity, PPV, NPV and 95% confidence intervals of 38.1% (18.1% to 61.6%) 85.7% (42.1% to 99.6%), 88.9% (54.6% to 98.2%), 31.6% (22.7% to 42.0%) respectively compared to VFS for identification of dysphagia (Table 3.8). Mean hours between SLTAx and VFS was 1.9 (sd 1.3).

Table 3-7 Accuracy of the DTNAx to gold standard VFS for the identification of dysphagia and aspiration.

Accuracy DTN vs VFS (N=47)	VFS Dysphagia	VFS - No dysphagia	Value	95% CIs
DTNAx Dysphagia	16	2	Sensitivity: **45.7%**	28.8% to 63.4%
			Specificity: **83.3%**	51.6% to 97.9%
			PPV: **88.9%**	68.2% to 96.8%
DTNAx No dysphagia	19	10	NPV: **34.5%**	26.2% to 43.9%
			Prevalence: **74.5%**	
			Accuracy: **55.3%**	40.1% to 69.8%

DTNAx, Dysphagia Trained Nurse Assessment; VFS, Videofluoroscopy; CIs, confidence intervals.

Table 3-8. 2 x 2 table comparing outcome of SLTAx and VFS in identifying dysphagia

SLT vs Gold Standard VFS (N=28)	VFS – Dysphagia	VFS – No dysphagia	Value	95% CIs
SLTAx Dysphagia	8	1	Sensitivity: **38.1%**	18.1% to 61.6%
			Specificity: **85.7%**	42.1% to 99.6%
			PPV: **88.9%**	54.6% to 98.2%
SLTAx No dysphagia	13	6	NPV: **31.6%**	22.7% to 42.0%
			Prevalence: **75.0%**	
			Accuracy: **50.0%**	30.7% to 69.4%

3.3.4 Diagnostic accuracy for aspiration

For DTNAx identification of aspiration sensitivity, specificity, PPV, NPV and 95% confidence intervals were 77.8% (40.0% to 97.2%), 81.6% (65.7% to 92.3%), 50.0% (32.0% to 68.0%), 93.9% (81.9% to 98.2%) respectively (Table 3.9). Of the seven false positives, six

demonstrated airway penetration (PAS 2-5) on VFS. For SLTAx identification of aspiration the diagnostic values were 80.0% (28.4% to 99.5%), 87.5% (67.6% to 97.3%), 57.1% (29.8% to 80.7%), 95.5% (78.3% to 99.2%) respectively (3.10).

Table 3-9. Accuracy of the DTNAx to gold standard VFS for the identification of aspiration.

DTN vs VFS (N=47)	VFS Aspiration	VFS - No aspiration	Value 95% CIs
DTNAx Aspiration	7	7	Sensitivity: **77.8%** 40.0% to 97.2% Specificity: **81.6%** 65.7% to 92.3% PPV: **50.0%** 32.0% to 68.0% NPV: **93.9%** 81.9% to 98.2% Prevalence: **19.1%** Accuracy: **80.9%** 66.7% to 90.9%
DTNAx No aspiration	2	31	

Table 3-10 2 x 2 table comparing outcome of SLTAx and VFS in identifying aspiration

SLT vs VFS (N=29)	VFS – Aspiration	VFS – No aspiration	Value 95% CIs
SLTAx Aspiration	4	3	Sensitivity: **80.0%** 28.4% to 99.5% Specificity: **87.5%** 67.6% to 97.3% PPV: **57.1%** 29.8% to 80.7% NPV: **95.5%** 78.3% to 99.2% Prevalence: **17.2%** Accuracy: **86.2%** 68.3% to 96.1%
SLTAx No aspiration	1	21	

Data from the DTNAx (n=47) closest in time to the SLTAx and VFS was also analysed, it is not presented because it differed very little from the above analyses.

3.3.5 Accuracy of recommendations

There was moderate to strong agreement between the DTN and SLTAx recommendations (Table 3.11). In addition, 81.4% of the DTN fluid recommendations and 81.2% of the diet recommendations were in absolute agreement with the SLT recommendations. Agreement between DTN and VFS recommendations were minimal to weak (Table 3.11).

Kappa's cut offs for what constitutes acceptable agreement for health research have been questioned. The original cut offs were 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as

substantial, and 0.81–1.00 as almost perfect agreement. However, McHugh 2012 demonstrates that clinical practice could be changed because of "substantial agreement" when 40% of results may not be reliable[226] and thus suggested stricter cut offs with which this data has been interpreted (Table 3.12).

Table 3-11 Absolute agreement between DTNAx outcome, SLTAx and VFS, and percentage of absolute recommendations.

Recommendations	Absolute Agreement % (n)	Weighted Kappa k (95% CIs)	Interpretation
DTNAx and SLTAx			
Fluids (N=70)	81.4 (57)	0.73 (0.59-0.87)	Moderate
Diet (N=69)	81.2 (56)	0.83 (0.73-0.93)	Strong
DTNAx & VFS			
Fluids (N=47)	59.6 (28)	0.37 (0.14-0.59)	Minimal
Diet (N=43)	55.8 (24)	0.47 (0.26-0.67)	Weak

DTNAx, Dysphagia Trained Nurse Assessment; SLTAx, Speech and Language Therapy Assessment; VFS, Videofluoroscopy; CIs, confidence intervals

Table 3-12 McHugh 2012 Kappa interpretation

Value of Kappa	Level of Agreement
0-.20	None
.21-.39	Minimal
.40-.59	Weak
.60-.79	Moderate
.80-.90	Strong
Above .90	Almost Perfect

3.3.6 Reliability

3.3.6.1 Inter-rater reliability

Inter-rater reliability for identification of dysphagia on the DTNAx was moderate k=0.62 (Table 3.13) with 81.0% absolute agreement. There was a trend for DTNAx1 to make more modified recommendations than DTNAx2 (Tables 3.13 A, B & C). To explore whether time between

assessments was a factor, the DTNAx data were grouped into 0-20 hours between assessments and >20 hours and agreement recalculated. Agreement was better in assessment when assessments were closer together in time (k = 0.72 (0.24-1.0) vs k = 0.50 (0.02-0.98)) suggesting time and spontaneous recovery explain the difference.

3.3.6.2 Intra-rater reliability

Due to limited number of reassessments by the same nurse (n=4) there was insufficient data to explore agreement statistics, however there was 100% agreement on presence of dysphagia and fluid and diet recommendations.

Table 3-13 Inter rater reliability between Dysphagia Trained Nurses for presence of dysphagia, fluid and diet recommendations.

	Comparison	Outcome	Kappa/ weighted kappa k (95% CIs)	Interpretation
Inter-rater	n=21	Dysphagia	0.62 (0.28-0.95)	Moderate
	n=21	Fluids	0.29 (0.08-0.50)	Minimal
	n=20	Diet	0.50 (0.24-0.77)	Weak

CIs; Confidence intervals

Table 3-14 A, B, & C Comparison of DTNAx1 and DTNAx2 data

A. 2 x 2 table comparing DTNAx 1 vs DTNAx 1 in detecting dysphagia

N=21	DTNAx 2 – Dysphagia	DTNAx 2 – No dysphagia	Absolute agreement Dysphagia 17/21 (81.0%)
DTNAx 1 Dysphagia	7	3	
DTNAx 1 No dysphagia	1	10	

B. Agreement of fluid recommendations from DTNAx 1 and DTNAx 2

FLUIDS (n=21)		DTN 2			
		L0	L2	L3	NBM
DTN 1	L0	11	1	0	0
	L2	4	2	0	1
	L3	0	0	0	0
	NBM	0	2	0	0

C. Agreement of diet recommendations from DTNAx 1 and DTNAx 2

DIET (n=20)		DTN 2				
		L7	L6	L5	L4	NBM
DTN 1	L7	11	1	0	0	0
	L6	1	0	0	0	0
	L5	1	0	1	0	0
	L4	0	1	1	0	1
	NBM	1	0	0	1	0

3.3.6.3 Reliability of VFS analysis

Inter-rater reliability was excellent for PAS scores (ICC=0.93 95% confidence intervals 0.87-0.96), and weak for MBSImP score k= 0.500 95% confidence intervals 0.44-0.56 with absolute agreement of 66.6% for component scores. There was 100% agreement on presence of dysphagia and aspiration.

Intra-rater reliability was excellent for PAS scoring (ICC= 0.92 95% confidence intervals 0.87-0.96) and moderate for MBSImP scores (k=0.76 95% confidence intervals 0.73-0.80) with 81.0% absolute agreement.

There was missing data on VFS analysis (Table 3.15), four participants triggered safety cut offs therefore boluses were not administered. Recording was an issue in one VFS so several boluses were not captured. Of the boluses that could be analysed, 92% of components were scored. The remaining components could not be scored due to VFS quality issues which included framing issues (structures not in view), or timing issues (process not captured as screening stopped early or started late). Table 3.16 shows that the lips were rarely in view in order to score component 1, and more oral stage components were missed than pharyngeal stage components.

Table 3-15 VFS data analysed

VF ID	Rater 1 Percent of boluses scored (/11)	Reason bolus not scored	Rater 1 % of Components scored	Inter-rater % of components scored (/152)	Intra-rater % of components scored (/152)
VF2	100 (11)		86 (130/152)	84 (128)	
VF3	100 (11)		97 (147/152)		
VF4	100 (11)		97 (147/152)		
VF5	100 (11)		96 (146/152)		
VF6	73 (8)	Not given - safety	66 (91/138)		
VF7	100 (11)		97 (148/152)		
VF8	100 (11)		99 (151/152)		
VF10	100 (11)		88 (133/152)		86 (131)
VF11	100 (11)		89 (135/152)		
VF13	55 (6)	Recording issues	88 (73/83)		
VF14	100 (11)		84 (128/152)		80 (122)
VF16	82 (9)	Not given - safety	98 (122/124)		
VF21	100 (11)		93 (141/152)		
VF22	100 (11)		93 (141/152)		
VF23	91 (10)	Not given - safety	96 (132/138)		
VF26	100 (11)		93 (142/152)		
VF27	100 (11)		91 (138/152)	95 (145)	
VF29	100 (11)		99 (150/152)	100 (152)	98 (149)
VF30	27 (3)	Not given - safety	71 (29/41)		
VF31	100 (11)		97 (148/152)		
VF32	100 (11)		93 (142/152)		
VF36	100 (11)		94 (143/152)		
VF38	100 (11)		93 (142/152)	94 (143)	93 (141)
VF43	100 (11)		93 (141/152)	93 (141)	93 (141)
VF44	100 (11)		89 (136/152)		
VF45	100 (11)		97 (148/152)		
VF46	100 (11)		93 (141/152)		
VF47	100 (11)		93 (141/152)		
VF48	100 (11)		97 (148/152)		
VF50	100 (11)		96 (146/152)		
Average % of components scored by Rater 1			92%		

Table 3-16 Missing VFS data by MBSImP component

Component number	Components	Missing scores
1	Lip closure	312
2	Tongue Control	31
3	Bolus preparation/mastication	35
4	Bolus transport/lingual motion	33
5	Oral residue	29
6	Initiation of swallow	36
7	Soft palate elevation	27
8	Laryngeal elevation	27
9	Anterior hyoid excursion	24
10	Epiglottic movement	24
11	Laryngeal vestibular closure	29
12	Pharyngeal stripping wave	28
14	Pharyngoesophageal segment opening	25
15	Tongue base retraction	24
16	Pharyngeal residue	4

3.4 Discussion

This study investigated the diagnostic accuracy of the DTNAx in identification of dysphagia and aspiration in acute stroke patients.

The DTNAx demonstrated excellent diagnostic accuracy in identification of dysphagia compared to the usual SLTAx. The diet and fluid recommendations from the DTNAx were closely aligned to the SLTAx recommendations. These results suggests that DTNs can accurately screen for dysphagia and offer appropriate diet and fluid recommendations to acute stroke patients on admission to hospital. SLTs can then follow up within 72hrs to provide ongoing specialist assessment, education and rehabilitation, adjusting diet and fluid recommendations as appropriate.

The DTNAx and SLTAx also demonstrated good accuracy in identification of aspiration on VFS. The positive predictive value was lower for both DTNAx and SLTAx suggesting assessors are

oversensitive (or cautious) in identifying aspiration, which is not uncommon in bedside assessments[227]. However, six of seven false positive cases from the DTNAx were found to show airway penetration on VFS. The DTNAx was not validated for penetration and/or aspiration because minor and shallow penetration (PAS = 2) is relatively common in normal swallowing thus not seen as an impairment or risk [219]. However, penetration, when deeper, in increased amounts and uncleared from the laryngeal vestibule, is uncommon in healthy adults and can be a safety concern[219, 228]. In addition penetration does not always result in a sensorimotor response such as cough [228].Therefore, all cases of penetration are unlikely to be identified on bedside assessment. With this in mind, the low positive predictor value is not unexpected and an over-cautious approach by both DTNAx and SLTAx is safer in terms of avoiding stroke associated pneumonia. Indeed, an accompanying high negative predictive value for aspiration (94%) means few false negatives, an encouraging result.

A meta-analysis of water swallow tests found a pooled sensitivity and specificity of 72% (95% CI 64– 79%) and 72% (95% CI 61-81%) respectively[229], suggesting that the DTNAx is superior to water swallow tests in the accurate identification of aspiration. Pooled sensitivity and specificity for aspiration for GUSS[200] was found to be 96.0% (CI 95% 90–99%) and 65% (CI 95% 47–79%), respectively but this should be interpreted cautiously as discussed in Chapter 2 [199].

The GUSS, VVST[178] and BESST[180] have also been validated for identification of dysphagia. The DTNAx showed more favourable sensitivity and specificity than the BESST (89.7 & 81.6% respectively) [180] and the GUSS (95.3 – 98.5% & <53.3-72.2% respectively) [184, 201]. The VVST demonstrated similarly high sensitivity and specificity to the DTNAx. However, significant quality issues have been identified with the VVST and GUSS studies. For example,

experts were used to conduct index tests. Included participants were already suspected of having dysphagia and in a number of studies assessors were not blinded. In contrast, this study used DTNs for the index test, which is how this tool is intended to be used. Participants in this study were representative of an acute stroke population and the VFS, DTNAx and 69% of SLTAx assessors were blinded. Tests, such as those mentioned above, that allow recommendations of intake when they have not been assessed, have been criticised as the safety and efficiency of swallowing differs between consistencies[167]. The DTNAx is distinct, only allowing recommendations for consistencies directly tested and deemed safe and efficient.

According to the VFS MBSImP thresholds for normal verses impaired swallowing, *all* participants in this study had a diagnosis of dysphagia. Increasing age and comorbidities will also contribute to changes in swallowing [25, 230]. Certainly, this may explain half of the fourteen false negatives identified by SLTs to have a very mild dysphagia thus scoring a DSRS of 0, but this doesn't explain the remaining half. Another explanation is that the thresholds for dysphagia were too conservative and there is in fact a greater degree of variation in swallowing in the normal population than is accounted for by the MBSImP. To date, there has been no normative data published regarding MBSImP. However, studies using MBSImP that included healthy participants have shown that up to 95% scored above the MBSImP thresholds on component scores [230, 231]. Further research gathering normative data for MBSImP across different demographics is warranted.

In the literature definitions of dysphagia and means to assess or quantify dysphagia vary. For example, in the Martino 2005 review paper so often quoted regarding the prevalence of post stroke dysphagia, it was found to be much higher in studies using instrumental assessment

than when using clinical assessments [57]. The definition and measures used in the studies presented varied greatly and in some cases were very limited. Either yes/no judgement of dysphagia by assessors viewing the VFS images, yes/no to presence of aspiration, which is only one aspect of dysphagia or the 4-Point Dysphagia Scale. This is a more in-depth qualification for dysphagia and included yes/no judgements on seven features, anterior bolus loss, delayed initiation of movement, uncoordinated initiation of oral transfer, delayed pharyngeal swallow, reduced laryngeal excursion, penetration into the laryngeal vestibule, aspiration and stasis. Pharyngeal delay was rated as mild (.45- to 2-second delay), moderate (3- to 5-second delay), or severe (6- second or longer delay). Dysphagia was rated on a scale of 0 (normal) to 4 (severe). Mild dysphagia (score 1) was classified by evidence of decreased oral stage transition, inconsistent mild delay in the pharyngeal swallow (.45 to 2sec), inconsistent mild-moderate stasis, or intermittent evidence of trace penetration into the laryngeal vestibule with immediate clearing. Moderate dysphagia (score 2) was classified by mild to moderate delay in the pharyngeal swallow (.45 to 5sec), decreased laryngeal elevation, or moderate stasis resulting in laryngeal penetration with stasis and/or two or fewer instances of aspiration of a single consistency. Moderate-severe dysphagia (score 3) was classified by a moderate to severe delay in the pharyngeal swallow (3 to 5sec or greater) or moderate to severe pharyngeal stasis resulting in consistent aspiration of a single viscosity. Severe dysphagia (score 4) was identified by a severe delay in the pharyngeal swallow (longer than 5sec) or moderate to severe stasis with build-up on consecutive swallows resulting in aspiration of more than one consistency [105]. No consideration was given to age related changes or variability in swallowing and the particular paper cited above used 81% weight to volume barium thus the results may be inflated.

Furthermore, in studies validating the VVST which used VFS, the following criteria was used to define dysphagia: impairment in efficacy constituted impaired labial seal closure, oral residue, pharyngeal residue, or piecemeal deglutition; and an impairment of the safety of swallow was considered when penetration or an aspiration was detected [182]. All factors were yes/no based on judgement by the assessor.

The GUSS validation studies used FEES as the instrumental assessment whereby criteria for dysphagia was a score of greater than 1 on the Fibreoptic Dysphagia Severity Scale (FEDSS) [201] [232]. A score of 1 constitutes no penetration or aspiration and not more than mild to moderate residue in valleculae or pyriforms. FEES is superior in examining the anatomy and sensitivity of the larynx and pharynx and may be able to judge residue and aspiration and penetration if not as good but perhaps better than VFS[233]. However, it cannot be used to make judgements regarding the oral stage of the swallow and what is happening during the swallow, thus VFS may be the preferred tool to answer whether oropharyngeal dysphagia is present or not. What can be seen from this study and previous studies is that more work is needed to decide what is assessed and how it is interpreted.

For purposes of validation in this study, dysphagia on VFS was re-defined as dysphagia requiring adaptation/modification. The definition of what constituted a safe consistency was prespecified by the research team based on PAS and key subsections of the MBSImP that are known to impact on safety and efficiency of the swallow. Despite this, the accuracy of bedside DTNAx and SLTAx in identifying dysphagia according to VFS remained low.

Whilst a moderate to strong agreement was found between the DTN and SLTAx recommendations, the accuracy of recommendations compared to VFS were poor. Possible explanations may be that thresholds were too conservative as discussed above. In addition,

the PAS scale does not account for the extent of material that enters the airway and some consistencies may have been deemed unsafe having scored a trace PAS=3 which may not necessarily be the case but highlights a critical area for further research. Another explanation is that the SLT and DTN bedside assessment recommendations were inaccurate in identifying consistencies that could be swallowed safely or efficiently. It is worth noting that none of the VVST or GUSS validation studies investigated accuracy of recommendation from the index test to the reference test as has been done here. A recent study found that 67% of clinical bedside SLT recommendations were changed, either made more or less restrictive when FEES was performed [234]. Clinical bedside assessments are limited in detecting silent aspiration [96], describing physiological impairments accurately [194, 235] and judging the effectiveness of compensatory strategies[119]. However, recommendations for oral intake are often made from bedside assessment as instrumental assessments are not always available, may be impractical and unlikely to be cost effective for making all management decisions. There is also evidence that behavioural interventions, including dietary modification derived from SLT bedside assessments in acute stroke, result in improved outcomes [236]. Furthermore, when VFS are used clinically, decisions on severity and suitable swallowing recommendations are made on the basis of the VFS result in conjunction with patient reports, clinical bedside assessments, and the impact on the patient's health and quality of life. Considering all of this, it is not surprising that the SLT and DTN recommendations don't agree with VFS outcomes alone.

It is worth noting that although over 81% of the DTNAx recommendations were in absolute agreement with SLT recommendations, there were around 19% that were not in agreement. Some of these recommendations by DTNs were more conservative i.e., consistencies were more modified. A more modified diet is unlikely to post increased safety or efficiency risks

than a less modified diet. For fluids, several studies have shown that as the viscosity increases, PAS scores decrease suggesting thickened fluids can be safer. However this is not always the case [237]. It is also certain that some of these DTN recommendations were less modified than the SLT. This will be in part due to participant factors such as neurological symptoms or fatigue improving or worsening. It could also be due to inaccurate DTN findings; however, these numbers are small. A further study looking at the outcomes of patients in the days and weeks after being assessed with the DTNAx could explore whether these small number of inaccuracies have a negative impact on patient's health.

Inter-rater reliability between DTNs was moderate. Due to clinical practicalities, the assessments were on average 19.6 hours apart with spontaneous swallow recovery in the early phase post stroke [238] leading to lower levels of agreement – the data support this with better agreement between closer assessments. In addition, the recommendations from the first DTNAx were more modified compared to the second suggesting an improvement in dysphagia over time. Therefore, these results may indicate a change in the patient's clinical picture rather than lack of reliability and highlights the challenge of establishing test-retest reliability in clinical measures where function can be changing rapidly. This sensitivity analysis demonstrates that some patients with dysphagia can rapidly improve in a short space of time, highlighting the need for regular SLT reviews in the acute stroke setting.

Inter-rater reliability for VFS MBSImP was weak. The raters, trained in MBSImP were required to attain competency using the tool, by completing an online training and reliability assessment and achieving over 80% agreement with the tool's authors. This cut off allows a less than perfect reliability in scoring, however not as low as 66.6% agreement as seen in inter-rater reliability in this study. It is clear that the MBSImP training alone may not be

sufficient to ensure accurate scoring between raters and further research group training is needed to calibrate scoring. Intra-rater reliability was better and reached the >80% reliability so this is unlikely to explain the lack of agreement between clinical assessment and VFS. Future studies may benefit from comparing scores between raters to agree on a final score adjudicated by a third rater if necessary, this final score is then used as the VFS data in the research [224]. Quality issues with the VFS images, despite pre-study training, resulted in missing data, but over 90% of the components were scored.

3.4.1 Limitations

The study was subject to a few limitations. Firstly, this was a small single centre study which can limit generalisability. VFS was not always possible due to availability and many participants with severe stroke symptoms were unable to tolerate the assessment. It was, however, vital to include more severe strokes to validate the DTNAx. The lower numbers for VFS and thus an even smaller number who were found to aspirate meant that results were less precise giving wide confidence intervals and reduced the power calculated in sample size calculations. However, the sample size was met for the SLTAx and the results demonstrate more precise results as predicted in the calculations. It is also reassuring that the DTNAx picked up the majority of participants with dysphagia that were then referred to SLT for ongoing management which may involve referral for instrumental assessment.

Similarly numbers were smaller for the second DTNAx causing less precision in the results, and in the case of intra-rater reliability, data were too few to analyse.

The SLTs did not use a standardised or validated bedside assessment to identify dysphagia, which is representative of usual care and SLTs undergo in-depth training and competency assessments to become experts in dysphagia assessment and management.

Lastly, the MBSImP was chosen due to its standardised protocol, analysis and training and has achieved favourable reliability and validity[122]. But due to the lack of normative data on which to define dysphagia, it has been limited in this study. However, there are no other psychometrically sound VFS analysis tools that would have been superior[120] which highlights the need for more research to define dysphagia from VFS.

3.5 Conclusions:

The DTNAx is comparable to SLT assessment in identifying dysphagia and making early management decisions regarding nutrition in an acute stroke unit. The DTNAx and SLTAx demonstrated good accuracy in identifying patients who aspirate on VFS but may judge airway penetration falsely as aspiration. Both the DTN and SLT assessments under-diagnosed dysphagia compared to the VFS, but this may be due to the methods for defining dysphagia on VFS. A good tool must also demonstrate clinical utility and cost effectiveness in addition to diagnostic accuracy; therefore, further research is needed to look at the outcomes of DTN assessed patients in the days and weeks post assessment and its cost effectiveness against other swallowing assessment pathways.

Chapter 4: The experiences of Dysphagia Trained Nurses in acute stroke

A version of this chapter has been submitted for publication:

- Benfield JK, Thomas SA, Hedstrom A, Bath PM, England TJ. Experiences of Dysphagia Trained Nurses in acute Stroke

Conference Presentations arising from this chapter:

- UK Stroke Forum 2020 Invited speaker Dysphagia Session The role of nurses in the early management of dysphagia in acute stroke

Contributions:

The author collated, analysed and interpreted the data and wrote the chapter. Dr Shirley Thomas advised on the qualitative methodology and reviewed the manuscript. Amanda Hedstrom reviewed the data and elicited themes as a second reviewer for reliability. The author presented the results nationally.

4.1 Introduction

In the UK, SLTs do not cover stroke units 24 hours a day and often are only commissioned to provide a 5-day service. Therefore, nurses are most often the profession that screens and assesses swallowing in acute stroke. The previous chapters have shown that nurses administering the DTNAx comprehensive swallow screening assessment with acute stroke patients has excellent diagnostic accuracy in the identification dysphagia. Nurses have been involved in the development of the DTNAx and other such tools and pathways [81, 239] and a survey conducted with nurses and SLTs working in Northwest UK found that screening for dysphagia was accepted as part of the nursing role [180]. However, little else is known about the experiences or opinions of nurses carrying out these swallowing assessments. It was also unclear whether the nurses using the DTNAx were using the tool as intended in the acute stroke pathway and if there are any barriers or challenges doing so.

4.2 Aim

The aim of this chapter was to understand the experiences of dysphagia trained nurses in acute stroke who assess swallowing and make early management recommendations using the DTNAx.

4.3 Method

4.3.1 Study Design

The study followed a thematic analysis approach [240] whereby Dysphagia Trained Nurses (DTNs) were interviewed to gain insight into their experiences and opinions of being a DTN and conducting swallowing assessments in acute stroke.

4.3.2 Participants

Ten nurses were approached and invited to participate from the Acute Stroke Unit (ASU) at Royal Derby Hospital and given verbal and written information regarding the research (Appendix 10). Nine DTNs were recruited for a single interview lasting up to 30 minutes; one declined to participate due to not wanting to be audio-recorded. Participants were selected by a combination of maximum variation sampling and convenience sampling [241] with the aim to have responses from all levels of nursing experience, different amounts of DTN experience, type of shift pattern and demographics. Table 4.1 gives the demographic information of the included nurses. Most nurses were female, UK trained, Band 5 or 6 and worked full time day, night or mixed shifts. There was representation, however, from two nurses who trained abroad, one male nurse and one part time nurse. Experience as a nurse ranged from two years to 30 years and experience as a DTN ranged from one to 15 years. Data was not gathered on number of years of experience on the stroke unit rather in other clinical settings. This sample was not proportionate to the actual population of DTNs working on ASU but represented some of the diversity.

4.3.3 Research team

The interviews were carried out by the researcher (JB) who is a doctoral student and a clinical Speech and Language Therapist on the ASU working alongside the participants. JB also coordinates the DTN training and audits the stroke dysphagia pathway. In order to lessen any effect of a power relationship between the interviewer and interviewees [241] the nurses were asked to be fully honest in their responses and they were reassured that the interviews were confidential and they could express any negative opinions they had without consequence.

Table 4-1. Demographic information for the Dysphagia Trained Nurses who participated in interview

Demographic		Numbers (%)
Sex	Female	8 (88.9)
	Male	1 (11.1)
Years qualified	0-5	3 (33.3)
	5-10	2 (22.2)
	10-15	2 (22.2)
	25-30	2 (22.2)
Where qualified	UK	7 (77.8)
	India	1 (11.1)
	Philippines	1 (11.1)
Band/Grade	5	4 (44.4)
	6	5 (55.6)
Full/Part time	Full time	8 (88.9)
	Part time	1 (11.1)
Shifts	Mix of days and nights	4 (44.4)
	Mostly days, occasional nights	3 (33.3)
	Only days	1 (11.1)
	Mostly nights	1 (11.1)
Years as a DTN	0-5	4 (44.4)
	5-10	3 (33.3)
	10-15	2 (22.2)

Table 4-2. Semi-structured Interview questions

Interview questions
1. When did you qualify as a nurse? _____and where??
2. How long have you been a DTN? _____
3. Are you …? Band 5 Band 6 Band 7
4. Do you work …? Mostly days Mostly nights Mix of days/nights
5. Are you…? Full time Part time
6. How often do you carry out a DTN assessment?
> 1 x week 1 x week 1 x fortnight 1 x month < 1 x month
7. What impact do you as a DTN have on stroke patients admitted to ASU?
8. What do you think of your role as a DTN within ASU?
9. Did you gain anything from the DTN training? If so what?
10. Did the training equip you to assess swallowing using the DTN assessment tool?
Yes No
Can you give me some more details?
11. How confident do you feel using the DTN assessment tool? Are there any scenarios where you feel more or less confident?
12. Do you receive any support as a DTN? Do you feel you need it?
13. What do you think of the DTN assessment tool's ability to identify dysphagia? Do you think you get an accurate picture of someone's swallowing using the DTN assessment tool?
14. How do you find assessing swallowing using the DTN assessment tool?
15. Is it always possible to follow all the steps of the assessment tool?
Yes No
Can you give me some more details?
16. What do you think of the DTN assessment paperwork? (Show paperwork)
17. Do you have any other comments?

4.3.4 Data collection

The interviews were semi-structured around a set of questions (Table 4.2) to ensure the most useful information was gathered. A pilot interview was carried out with one of the DTNs, the recording was listened to and reflected upon to ensure that the quality of questions and manner of asking questions was appropriate and the information received was focused [242]. From this, several questions were rephrased and probing questions were added to the original interview to help draw out information in subsequent interviews.

4.3.5 Setting

The interviews were carried out during the nurse's normal shifts on ASU. This was negotiated on the day with the coordinating nurse and the DTN and only conducted if there was sufficient ward cover. The interviews took place in quiet rooms, off the ward, with no interruptions and lasted up to 30 minutes long. The interviews were audio-recorded and later transcribed by the interviewer.

4.3.6 Ethics

The study received ethical approval from the West Midlands Research Ethics Committee (17/WM/0209) and locally from the University Hospitals of Derby and Burton Trust Research and Development Team. Participants gave written consent to participate (Appendix 11). Voice recordings and transcripts were anonymised. The Consolidated criteria for Reporting Qualitative research (COREQ) has been used as a checklist to guide reporting (Appendix 12) [243].

4.3.7 Sample size

A sample size of ten was estimated to be sufficient given previous research suggesting no new themes emerge after 6-12 interviews [244]. The interview number where new themes were documented was recorded to explore data saturation. No new themes or sub-themes were coded or identified after the sixth participant. Considering the interviews were conducted across a broad, representative demographic of nurses it can be concluded that data saturation was reached [245].

4.3.8 Data analysis

An essentialist/realist epistemological approach was used and the analysis aimed to give a rich description of the data set [240]. Full thematic analysis was conducted by the main researcher (JB); a second member of the research team (AH) also read the transcripts and identified key and common themes to improve reliability of the research [246]. The Braun and Clarke 2006 six phases of thematic analysis was used to analyse the data. In Phase One, JB familiarised herself with the dataset. Phase Two, coding; a series of nodes were identified *a priori* based on the overall research question and specific interview questions, including the role, training, support, assessment process and paperwork. Initially, using NVivo 12 Version 12, data were coded into these a priori nodes deductively and new nodes were created inductively as they were identified in the data [247]. In Phase Three and Four, JB reviewed the nodes to search for themes and organised the coded data under each theme, adding sub-themes where indicated. The themes from both reviewers were compared, AH identified all the themes that JB had coded only adding two subthemes which were agreed upon and added to the thematic framework. In Phase Five, themes were described and summarised and to increase reliability the results were shared with participants for comment[248], none of them

disagreed with its content. A final revision of theme names was carried out and then in Phase Six the report was written, presenting and describing the themes and giving relevant extracts from the data.

4.4 Results

The thematic framework with its themes and sub-themes is shown in Table 4.3.

Table 4-3. Themes identified from nurse interviews.

Themes	Sub-themes
Nurses value the role	Speech and Language Therapists (SLTs) as experts, DTNs supporting
	DTNAx where
	Enhances and or extends the nursing role
	Positive impact on patient's comfort, wellbeing and health
	Expedites patient care within the stroke pathway
	Valued
	Better now
Challenges and deviations from the pathway	Assessing patients already eating and drinking
	Assessing patients with no or mild unrelated problems
	Medical intervention
	Time pressure to complete the Dysphagia Trained Nurse Assessment DTNAx
Easy to use and accurate assessment tool	Accurate
	Easy or Step by step
	Lengthy
Challenges and adaptations with different patients	Challenges to completing the DTNAx
	Differences in administration of the DTNAx
	Changes due to International Dysphagia Diet Standardisation Initiative
Training is essential, but updates are appreciated	Gain additional knowledge
	Developing specialist/intuitive skills
	Need for regular training updates
Confidence comes with practice and experience but support there when needed	Comes with practice and experience
	Confident
	Dips in confidence
	Fear
	Patient differences
	Self-awareness
	Support from SLTs and other DTNs

4.4.1 Nurses value the role

The DTN role was highly valued by the nurses, not only for enhancing professional development, but also as it has a positive impact on patient's health and quality of life and assisted in the stroke pathway.

> *"It's a nice skill to have as a nurse anyway, but especially if someone is working in stroke, it's essential really and every RN [registered nurse] should have it that's going to be working in stroke or rehab"* Nurse 4.

> *"Generally, when the patients come up, they have been in A&E for hours a lot of the time and they haven't had anything to eat and drink and they are hungry, so when they come up all they want to do is eat and drink"* Nurse 6.

Nurses reported that by carrying out the DTN assessments, earlier decisions could be made about feeding, hydration and medication routes.

> *"So if they come in a Saturday morning better than them waiting until Monday because they always come up thirsty and starving and it's the first thing people ask for is a drink always. And then we know they can whatever consistency they go on to be able to have the medications they need as well, it's better."* Nurse 4

For all interviewees, DTN assessments were seen as an essential role in HASU following direct admission. To some it was exclusive to HASU but to others it was also important for assessing patients later in the rehabilitation pathway due to their evolving swallow status.

> *"It's vital that you need to be DTN trained because it's not only HDU, it's the rest of the ward. And patients are constantly getting better, patients get poorly".* Nurse 7

For more senior nurses where they spend periods of time coordinating the flow of patients through the unit, they may not perform as many assessments.

> *"It really varies from week to week, some weeks I do daily, but some weeks where I coordinate and I'm not getting that much chance to do it. Mostly 2 or 3 a week at least ".* Nurse 5

It was also clear that a DTN was deemed as a supporting role to the SLTs, who were described as the experts in dysphagia by a number of nurses.

> *"we do look to you guys, SLTs, for your expertise"* Nurse 7

The nurses that had been a DTN for many years highlighted that the role is better now as there are many more DTNs trained than in the past. They described a time when they were the only DTN on shift with some resentment, reporting that much of the shift was taken up by completing swallow assessments.

> *"I was straight in being DTN trained because there weren't as many people then, so you felt like it was all you were doing was the swallow assessments. Which is fine when they're needed but when you've done so many in a day, it's distracting you from the other stuff you need to do"*. Nurse 4

4.4.2 Challenges and deviations from the pathway

The DTN role was viewed as having a positive impact on the stroke pathway. However, when a patient arrived to the ward who hadn't followed the usual swallowing pathway and they were already eating and drinking normal diet and fluids without prior assessment, the use of the DTN assessment was questioned.

"I have people, they've been eating and drinking downstairs on MAU [Medical Assessment Unit], it's really busy, you've got 50 million people, you order a normal diet and you go from there. I know that I shouldn't but I've done that before. Sometimes it's really difficult when you know that they've been eating previously before they come up but I need to do it, it's got to be done" Nurse 3

A few nurses challenged the use of the DTN assessment in patients with mild unrelated symptoms or no symptoms; two suggested they might skip parts of the assessment if it was busy or if the patient wasn't so happy to comply.

"I can't understand why we do DTN on people with some symptoms. I can understand if a patient has got speech problems or swallow problems and that triggers on the NIHSS score. But a patient has just got a little bit of limb weakness or sensory weakness, we're doing a full DTN assessment on them" Nurse 1

Decisions by the medical team were on occasion also reported to impact on whether the assessment was carried out in the way intended.

"Sometimes the doctors might push you to do an assessment, but it's knowing when to say no, actually when you need to and knowing that you could be causing harm if you don't do it properly" Nurse 8

4.4.3 Easy to use and accurate assessment tool

The majority of nurses reported the assessment being easy to follow and progressed in a step-by-step way.

"It's good because you follow it and you can't go wrong … because it's laid out in front of you" Nurse 4

They felt the tool was accurate at the time of the assessment but raised concern that a patient's swallow status might soon change, leading to conflicting results with subsequent SLT assessments.

> *"Nine times out of ten, if someone is going to struggle with their swallow I think it picks it up quite quickly … there was a couple of times where I've assessed somebody and they've been normal diet and fluids or like level 2 fluids and then sometimes later on in the day when they are more fatigued they start to struggle and then I've reassessed them or I've made them NBM and put them down for you to review the next day"* Nurse 8

A couple of nurses thought the assessment was lengthy, taking around 20 minutes to complete, particularly when the unit was busy with frequent admissions.

Most nurses said the paperwork was straightforward, a few individuals mentioned aspects they found less clear or frustrating, but no specific common theme was identified.

> *"Structured. Very easy. It's a bit of a tick box exercise. So you tick boxes and make comments."* Nurse 1

4.4.4 Challenges and adaptations with different patients

Nurses reported variation in how they conducted the assessment, with some following it step by step, others doing it from memory. They reported having to adapt to patients because of dietary requirements, language barriers, difficulties understanding or completing some of the subsections.

"Sometimes supplies have been a bit awkward to get or if they have an allergy. There are some things that we can't help but we don't miss a step. We sometimes have to improvise" Nurse 1

"I find the assessment good. It's only in English. For our other patients that can't speak English it might be good to have something in different languages … but you do a lot of gesture." Nurse 7

Some reported skipping components of the assessment due to several reasons, ranging from availability of food items, patient consent, patients having difficulty following instructions, other dietary restrictions or due to time pressures.

"[When its busy] I've missed out a few bits, I've just gone straight to normal diet but I've watched them and gone through everything. And I don't tell anyone else to do that I've just took it upon myself to do that" Nurse 3.

They reported having to get used to a few changes over recent years due to a move from the UK National descriptors to the International Dysphagia Diet Standardisation Initiative (IDDSI) framework.

4.4.5 Training is essential, but updates are appreciated

The training was viewed as highly beneficial, acquiring and learning a new skillset. It was seen as essential for being a DTN but some nurses also felt it deepened their understanding of stroke aetiology and management.

"*I learnt a bit about the anatomy of the swallow, because before I had the training I didn't really know. Particularly in stroke, why we do it and how that can benefit the*

patient. I think if you've not had that training you don't fully understand the implications of it. It's good to have." Nurse 8

The training and subsequent experience has helped many develop specialist and intuitive skills in dysphagia.

"*you know really yourself, when you looking at the patient and the sound when to carry on and when to stop*" Nurse 2

"*You do a lot with your hearing, and you hear an odd cough and you think what's going on here or what's going off over there. These things come with time and experience*" Nurse 7

Many of the nurses felt that regular updates for DTNs were necessary to maintain skills, confidence and learn about any changes in protocol. Some expressed the need for continuing education or training, others valued an update they had recently attended.

"*could do with a refresher, I don't know if it's every year or every three years but it's a good update for anyone who's dysphagia trained*" Nurse 2

4.4.6 Confidence comes with experience

Confidence improved with practice, some nurses initially feared performing the assessment, but with experience the majority felt assured. There are reported reductions in confidence related to frequency in performing the assessments or approaching patients with additional co-morbidities.

"the more I do it the more confident I feel" Nurse 8

> *"there's times when … I'm not confident about what I found because the patient … seemed a little bit complex and maybe I sometimes worry are they not showing signs of aspiration*" Nurse 4

Despite feeling confident they also recognised when to ask for help or stop the assessment if they were unsure, demonstrating awareness of their limitations.

> "*Yeah confident, but if I ever have any issues then I just stop the assessment and I document everything. This week I've had a couple of patients that I've had interesting experiences with and I've asked a colleague to come and see because I'm a bit unsure*" Nurse 1

All the nurses described adequate support in the role from SLTs but also from more experienced DTNs. They related that the SLTs and senior DTNs were approachable and accessible. Support was sought on the ward as required and in the form of discussing assessment findings or requesting a second opinion from another DTN.

> "*Yeah, if you don't know what to do you can ask the senior staff as well, or an SLT*" Nurse 9

4.5 Discussion

With training, nurses can develop skills in dysphagia assessment and management and having nurses trained in dysphagia is beneficial towards adhering to best practice in the acute stroke pathway. Given there has been no research to date regarding the opinions of nurses in such a role, nurses clinically active in acute stroke care were interviewed and asked to share their experiences.

The interviews highlighted that nurses positively valued being a DTN. The DTN role can be seen as an extended nursing role and studies have found that nurses value additional responsibility, as has been found with prescribing [249], thrombolysis [250] or developing another speciality in their field of practice[251].

The fear some of the DTNs experienced when starting out was not specific to assessing dysphagia, but to taking on new skills. This was also found with nurses who take on thrombolysis responsibilities in acute stroke [250]. Workload and time pressures often impaired their ability to fulfil the role, as also seen in previous studies assessing the responsibilities of nursing on the HASU.[250].

Improving patient care was seen as an important benefit of the DTN role. Quantitative studies have shown that early screening reduces pneumonia in acute stroke [252]; however, the nurses interviewed identified other benefits such as patient comfort and early medication administration. Extended or specialist roles can mean that nurses can offer continuity of care to their patients, which is perceived as beneficial to the patient's quality of life [249-251].

There is limited documentation in the literature of the role and responsibilities of a dysphagia trained nurse or in fact how comprehensive dysphagia assessments such as the DTN are used in practice. This study shows that DTNs may also have a role after patients leave the hyperacute unit due to the complexity of swallow recovery. This is also the case for other comprehensive swallow assessments such as the Volume Viscosity Swallowing test (V-VST) [179]. Further research is indicated to understand the role of dysphagia trained nurses and how they fit into the stroke pathway in other health care settings.

Assessing patients with no, mild or unrelated symptoms using a comprehensive swallowing assessment was viewed as unnecessary in some cases and, consequentially, adherence to the

assessment proforma was reduced. Water swallow tests are also commonly used as screening tools in the stroke pathway. These tools have good sensitivity in identifying dysphagia for this group of patients [253]. Many of these screen out patients with solely oromotor dysfunction or speech difficulties, assessing only those with no, mild or unrelated symptoms so they tend to have lower specificity [253]. Therefore, a 2-stage test, whereby only those failing a water swallow test are assessed with a more comprehensive test, may be more practical, acceptable and time efficient to carry out.

The DTNs are trained up to a level of competency in the Interprofessional Dysphagia Framework whereby they can complete a protocol guided assessment [86]. The nurses reported that it wasn't always possible to follow the protocol, and they had to adapt it to certain patients such as those that cannot follow instructions, have allergies or organisational reasons such as limited range of foodstuffs on offer. The level of competency they achieve includes learning key knowledge about swallowing and dysphagia. Given the findings of this research, this training is essential as it is likely they have to pragmatically deal with situations that might occur in practice where they have to adapt and deviate from the strict proforma. Of note, validation of the DTN assessment has been performed in English but not in other languages [254].

The nurses perceived the role as complementary rather than as a replacement to the SLT role. It is worth highlighting that DTNs are trained to use diet and fluid modification to compensate for dysphagia where this demonstrates reduced risks of aspiration and choking [237, 255]. The nurses are not trained in other adaptations (for example, swallowing strategies, carbonation, use of cups, transition foods) or for use of instrumental assessment, longer term management or planning dysphagia interventions. For some patients, diet modification is not

acceptable but all of these patients go on to be managed by the SLT for reassessment and review of the current management with the aim to achieve normal diet/fluids where possible.

The Interprofessional framework [86] lays out that training is necessary to achieve the Foundation Dysphagia Practitioner level and that knowledge and competency needs to be assessed. The nurses that were interviewed stated that training was essential for the role, which has been indicated as a factor that improves nurses' education and improves the transfer of knowledge into practice [256]. Competency based education is essential in developing healthcare staff to work successfully in a modern healthcare setting [257] and also increases satisfaction with training and transfer of skills[256]. An environment where there is support from peers as well as assessors or clinical educators as described by the nurses also contributes to successful learning and transfer of skill [256]. Maintaining skill, knowledge and competence is the backbone of all registered healthcare professionals, built in to registration with the Health and Care Professions Council and with professional bodies. Little is known about whether dysphagia trained nurses maintain their knowledge and skills over time nor how many assessments they need to perform per year to maintain competence. However, considering this was valued by the nurses, regular updates or refresher courses may be beneficial for reassurance [258], improving confidence, self-efficacy and perceived competence [259]. Further studies could explore the efficacy of such updates to inform their mode of delivery, content and frequency.

4.5.1 Limitations

Although no new themes emerged after six interviews suggesting data saturation was achieved, principles such as an initial analysis sample and stopping criteria which help to strengthen claims of saturation [245] were not agreed prior to conducting the study.

There may have been a power relationship between the interviewer and interviewees due to clinical role held by the interviewer. Considering the DTNs shared their experiences of when they had to deviate from the DTNAx pathways and protocol and there were comments that could be perceived as critical, it is likely that this relationship was overcome by the reassurance given by the interviewer.

The interview questions set a framework for the themes that were found in the data. However, the questions were designed to be neutral so that the nurses could express their opinions within the framework and several unexpected themes and subthemes were identified. Nurses also had the opportunity to express other thoughts and opinions in open questions. Other methods such as focus groups or observing practices in hyperacute stroke units may reveal other themes outside this framework.

This study captures the opinions and experiences of DTNs in only one hospital using the DTNAx tool. This particular tool is not currently used in other settings; therefore, it would be difficult to generalise the results to other stroke services and to the use of other tools. It does, however, give insight into key areas that specialist nurses reflect upon and gives a framework to conduct further research.

4.5.2 Conclusions

Dysphagia Trained Nurses in an acute stroke setting value their role and the training they receive to assess patients' swallowing. They found the assessment tool easy to use and being able to assess swallowing in the stroke unit was beneficial for patient's health and wellbeing. Sometimes the role was challenging but nurses developed skills and knowledge to overcome these barriers through accessing support from more experienced staff. Further research is

needed to understand the impact dysphagia trained nurses can have on the outcomes of stroke patients.

Chapter 5: Does therapy with biofeedback improve swallowing in adults with dysphagia? A systematic review and meta-analysis

A version of this chapter has been published:

- Benfield JK, Everton LF, Bath PM, England TJ. 2019. Does Therapy With Biofeedback Improve Swallowing in Adults With Dysphagia? A Systematic Review and Meta-Analysis. Archives of Physical Medicine and Rehabilitation. 100 (3):551-561.

Conference presentations

- European Society for Swallowing Disorders (ESSD) 2017 Poster presentation for A Systematic Review and Meta-Analysis of Biofeedback in dysphagia therapy.
- UK Stroke Forum (UKSF) 2017 Oral presentation & award for Highest Scoring AHP Abstract for A Systematic Review and Meta-Analysis of Biofeedback in dysphagia therapy.

Contributions:

The author performed the searches, carried out data extraction, analyses and wrote the manuscript. Lisa Everton, carried out separate searches and data extraction and reviewed the manuscript as a second reviewer and collaborated with the author on decisions regarding which studies met the inclusion criteria. Dr Timothy England settled any disagreements. The author presented the results nationally.

5.1 Introduction

Biofeedback in swallowing therapy is not routinely used to augment dysphagia therapy [165] nor is there national recognition and guidance regarding its use. However, it is gaining more interest and several commercially available biofeedback instruments and software are on the market and so there is a need to evaluate its effectiveness. sEMG is the most commonly documented biofeedback tool in swallowing, but other instruments and a range of software options are available. Little is known about which exercises or interventions are best augmented by biofeedback and how they should be delivered to give the best outcomes.

5.2 Aims

The aim of this chapter was to conduct a systematic review and meta-analysis to describe the current evidence on the effects of dysphagia therapy with all types of biofeedback in adults with dysphagia of any aetiology in order to discover the most superior methods. This was kept broad rather than specific to one type of biofeedback and one aetiology as the literature was predicted to be sparce. This review aimed to answer the following questions in adults with dysphagia: Does biofeedback paired with dysphagia therapy, as compared with no biofeedback, improve (1) Functional swallowing outcomes? (2) Clinical outcomes? (3) Swallow physiology? It also aimed to discover the protocol and dosing that gave the best outcomes for patients.

5.3 Methods

The protocol was registered with Prospero (2016:CRD42016052942) in December 2016. Studies were eligible for inclusion if they were full text, English language studies that involved dysphagia therapy using biofeedback in adults with any aetiology resulting in acquired

oropharyngeal dysphagia and reported pre- and post-swallowing measures and/or clinical outcomes. Two independent reviewers (JB & LE) conducted electronic searches from when records began until December 2016 of the following databases: Cochrane Stroke Group Trials Register, MEDLINE, EMBASE, CINAHL, Conference Proceedings Citation Index- Science (CPCI-S) and Web of Science. Reviews of reference lists, conference abstracts and internet searches were conducted to ensure inclusion of unpublished or ongoing trials. Authors were contacted where partial or incomplete data were not available. An example of the search strategy for the MEDLINE search is included in Figure 5.1.

Figure 5-1. Search strategy for MEDLINE

1.	exp Deglutition Disorders/
2.	oropharyngeal dysphagia.mp.
3.	oro-pharyngeal dysphagia.mp.
4.	dysphagia.mp.
5.	'swallowing impairment'.mp.
6.	deglutition disorder.mp.
7.	1 or 2 or 3 or 4 or 5 or 6
8.	exp Biofeedback, Psychology/
9.	biofeedback.mp.
10.	Feedback, Physiological/ or Feedback/ or Feedback, Sensory/ or Feedback, Psychological/
11.	feedback.mp
12.	'skill therapy'.mp.
13.	(swallow* adj3 (therap* or exercise* or intervention* or rehabilitat* or train*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
14.	8 or 9 or 10 or 11 or 12 or 13
15.	exp Deglutition/
16.	deglutition.mp.
17.	swallow*.mp.
18.	15 or 16 or 17
19.	7 and 14 and 18
20.	limit 19 to (english language and humans)

5.3.1 Study selection

Two reviewers (JB and LE) searched the title and abstracts of the studies and excluded those that were not relevant. If there were any doubts the full text was sought. Once the full text was obtained the same reviewers selected the relevant studies for (1) A descriptive analysis of the types and application of biofeedback used in dysphagia therapy, and (2) Those meeting criteria for inclusion in a meta-analysis. Any disagreements were resolved with a third reviewer TE. Only those with a non-confounded control group and outcome data were included in the meta-analysis.

5.3.2 Data acquisition

Data were extracted using a predesigned and piloted proforma by one reviewer, JB and then verified by a second reviewer, LE. (Appendix 13). Authors were contacted if data were not available. TE resolved any discrepancies.

5.3.3 Risk of bias

Randomised control trials (RCTs) were assessed for risk of bias and quality as recommended in the Cochrane Handbook.[260] This included assessing methods of randomisation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and selective outcome reporting. Non RCTs were assessed using a combination of different tools for non RCTs and observational studies [261-263] and included assessing quality of study designs for small N and N=1 studies, data analysis, generalisability, replicability, blinding, incomplete and selective reporting.

What qualified high risk of bias/ low quality or low risk of bias/good quality is summarised in Appendix 14.

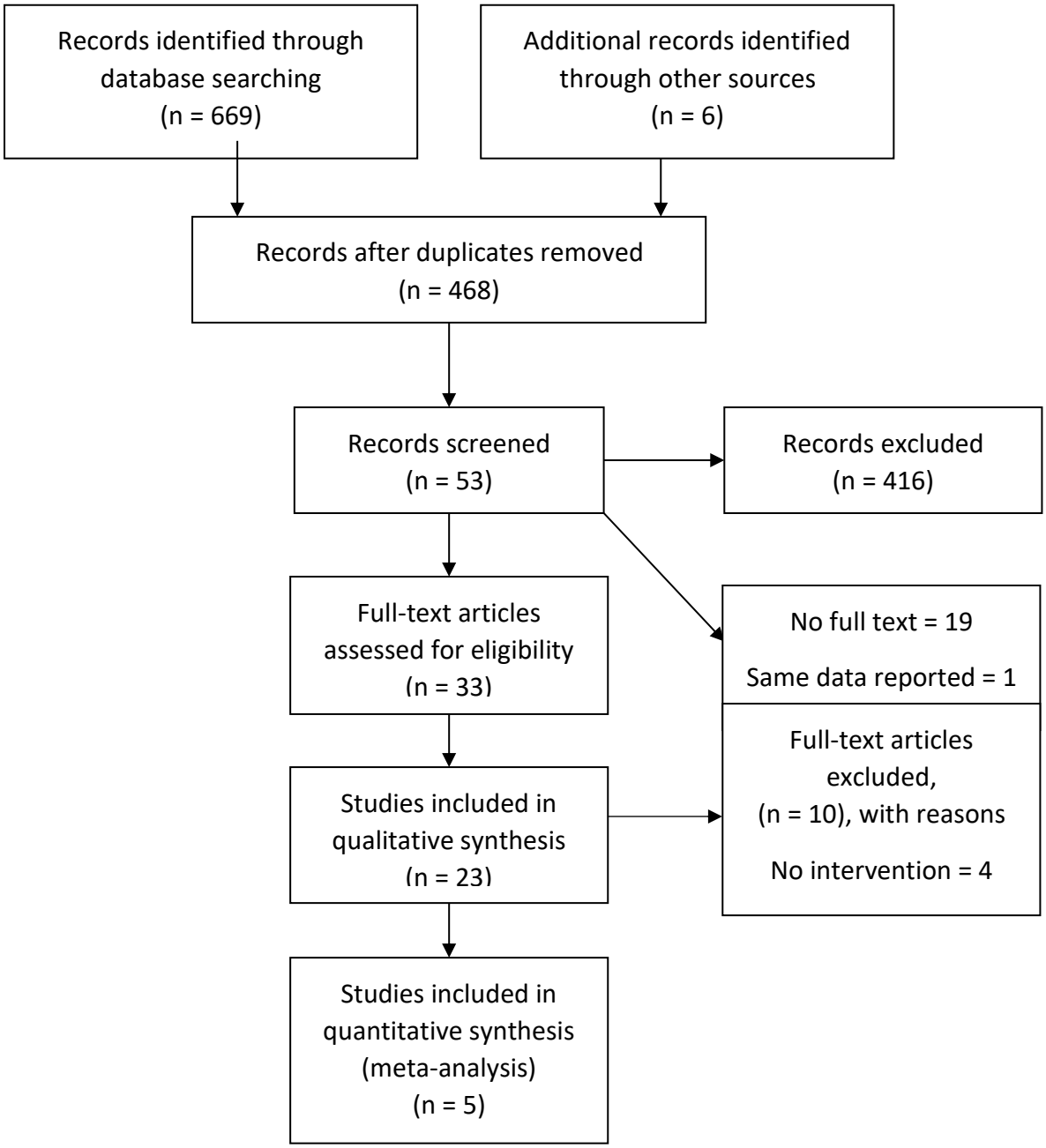
5.3.4 Statistical analysis

Review Manager (version 5.3) was used to derive odds ratios (OR) and confidence intervals (CIs) for dichotomous data and mean difference (MD) and CIs for continuous data. Study data were combined if the outcome measures used were comparable. In the Aoki 2015 study the mean and standard deviation (SD) were estimated from the median and range using published formulae [264]. Heterogeneity was assessed between different studies for each measure. Sub-group analysis was planned to examine whether biofeedback type, dose, aetiology of dysphagia or setting made a difference to outcome. The study was reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement (Appendix 15) [171].

5.4 Results

Initial searches identified 669 articles, and a further six were found through searching grey literature. After screening titles and abstracts, full text was sought for 53 studies. One full text article could not be obtained but there was sufficient detail in the abstract to be included in our analysis. [265] Of those, 23 were suitable for inclusion in a qualitative synthesis and 5 met the criteria for inclusion in the meta-analysis (Table 5.1, Figure 5.2).

Figure 5-2 Study flow diagram



5.4.1 Study characteristics

Twenty-three studies (n=448 participants) described dysphagia interventions with biofeedback in adults with structural, neurological and psychological dysphagia (Table 5.1). The three main types of biofeedback used were surface electromyography (sEMG, n=164), accelerometry (n=150) and tongue manometry (n=67). Less frequent forms of biofeedback included videoendoscopy (n=33), respiratory plethysmography (n=30) and external laryngeal manometry (n=4). There was no type of biofeedback exclusive to a specific patient group. Dosing and frequency of therapy varied across studies and across types of biofeedback; from four to 72 sessions carried out twice daily to fortnightly.[141, 216, 266, 267] Over 80% of studies reported two or more sessions per week. Overall, treatment sessions varied in length across study and type of biofeedback and lasted between 20-60 minutes with 45-60 minutes being the most common (50%).

5.4.1.1 *Accelerometry*

Five studies used accelerometry as a means of biofeedback. This consists of a small accelerometer being placed just above the thyroid cartilage. It measures the epidermal vibrations caused by the internal sounds and vibrations of the superior/inferior and or anterior/posterior movements of the hyoid and larynx during swallowing.[268] The vibrations are converted into a voltage signal, which the patient can use as visual feedback to facilitate their swallowing therapy. In three of the studies, feedback was presented as a graph on a computer screen with instruction to match the shape of a signal derived from a normal swallow.[269-271] In one study, the signal from the accelerometer was converted into an animation of a frog swallowing a mosquito at different locations on a screen. [272] The target

was adjusted based on performance. Another study used signals from accelerometry and surface electromyography (sEMG) in a similar virtual reality game.[273] Only one of these studies had a control group, [272] which reported that accelerometry significantly improved functional intake (functional oral intake scale, FOIS, p=0.014) and hyoid displacement (p=0.07) compared to control which received the same intensity of exercise without biofeedback. The other four accelerometry studies were of lower quality and also reported functional improvements in swallowing following the therapy.

5.4.1.2 Tongue manometry

Five studies used tongue manometry for biofeedback.[266, 274-277] This intervention consists of using a 2cm x 1cm x 0.5 cm air filled pressure bulb which acts as a pneumatic pressure sensor and measures isometric tongue strength. The bulb is placed on the tongue and the participant is instructed to push the tongue against the hard palate. The pressure generated is measured by a manometer and the signal can be displayed graphically on a screen to give patients biofeedback. Four studies used the Iowa Oral Performance Instrument (IOPI) [266, 274, 276, 277] and one used a Japanese version manufactured by Japan Medical Supply Ltd (JMS).[275] Robbins and colleagues used isometric anterior and posterior tongue strength exercises with the aim of increasing muscle strength and mass to lead to improvements in functional swallow.[266] The other four studies used isometric tongue strengthening, tongue strength accuracy exercises and tongue strength during saliva swallow exercises.[274-277] One study used a control group which received tongue exercises without biofeedback at the same intensity.[275] They described significant differences in mean change between treatment and control groups on maximum isometric pressure (p=0.03), swallowing tongue pressures (p=0.014) and motor function of swallowing structures – Mann

Assessment of Swallowing Ability (MASA) (p=0.04), but no significant differences between groups on swallow function. Four other studies of poor design reported positive outcomes in tongue strength[266, 274, 276, 277] . Moreover, reductions in vallecular[276] and pharyngeal wall residue[266] were observed on videofluoroscopy but the findings are contradicted in other studies where residue scores were neutral[266] or worse[274]. Only one of the studies described a positive functional swallowing outcome, [266] but no recognisable or specific outcome measures were presented.

5.4.1.3 Surface Laryngeal Manometry

One study used an air-filled balloon fixed externally to the cervical region to measure changes in pressure during swallowing.[278] Participants practised an effortful swallow and were given numerical feedback about their performance. It was a small study and there was no control group but the four patients with dysphagia secondary to Parkinson's reported improvements in swallow function following the intervention.

Table 5-1: Summary of included studies

Author	Biofeedback device	N	Exercise	Aetiology	Intensity	Frequency	Duration	Outcomes
Aoki 2015* [275]	Tongue manometry - JMS	34	TS and ES	23 stroke 11 mixed aetiology	45 mins	5 days/ week	3 weeks	Improvement in tongue strength and swallow physiology (MASA) post therapy, (but no significant difference between groups). Control group received the tongue exercises at the same intensity.
Athukorala 2014 [279]	sEMG	10	SS	Parkinson's Disease (PD)	60 mins	5 days/ week	2 weeks	Improvement in swallow physiology (timed swallow test and VFS) post therapy
Bogaardt 2009 [267]	sEMG	11	MM	stroke	20 mins	1-2 x fortnight	4-24 weeks	Improvement in swallow function (FOIS) and tube status post therapy
Bryant 1991 [280]	sEMG	1	MM and ES	Head & Neck Cancer (H&N Ca)	no info	3 x week	10 weeks	Subjective improvement in swallow severity and tube status
Carnaby-Mann 2009 & 2010 [a] [281, 282]	sEMG	24	MM and ES	mixed	60 mins	5 x week	up to 3 weeks	Improvement in swallow function (FOIS) and tube status post therapy (less improvement than case group)
Crary 2004 [283]	sEMG	45	Fixed swallow protocol	mixed	50 mins	5 days/week	3-4 weeks	Improvement in swallow function (FOIS) and tube status post therapy
Denk, 1997* [284]	Videoendoscopy	33	MM, ES, SGS, SSGS	H&N Ca	45 mins	2-5 days per week	up to 6 months	Improvement in tube status post therapy - no significant difference between groups at the end of the study (6 months). The control group received the same intensity and type of intervention without biofeedback.
Felix 2008 [278]	External laryngeal manometry	4	ES	PD	no info	5 days/week	2 weeks	Subjective improvement in swallow function post therapy
Hageman DASI web [271]	Accelerometry	103	SS	mixed	no info	Unknown	3 months	Improvement in Swallow Function and Pneumonia Risk scale - 92% made average of 2-point improvement post therapy
Haynes 1976 [285]	sEMG	1	Relaxation	Psychogenic dysphagia	30 mins	1-2 x week	11 weeks	Subjective improvement in swallow function post therapy
Huckabee 1999 [286]	sEMG	10	MM and ES, Shaker, Masako	Brainstem injury	60 mins	2 x day	5 days	Improvement in swallow function (own scale) and tube status post therapy
Huimin 2015* [†] [265]	sEMG	36	Functional swallow training	Stroke	Unknown	6 days/week	4 weeks	Improvement in swallow physiology (pharyngeal transit time, UES opening and maximum hyoid displacement compared to control group (same intervention with no biofeedback)

Author	Biofeedback device	N	Exercise	Aetiology	Intensity	Frequency	Duration	Outcomes
Krishnan 2013 [270]	Accelerometry	1	SS with target	PD	30 mins	3 x week	2 weeks	Subjective improvement in oral intake post therapy
Li 2016* [272]	Accelerometry	20	SS, ES & MM with targets	stroke	60 mins	3 x week	5-6 weeks	Significant improvement in hyoid displacement, function (FOIS) and tube status compared to control group (same intervention with no biofeedback)
Li 2016 [273]	Accelerometry & sEMG	21	SS with target	mixed	60 mins	3 x week	5 weeks	Improvement in swallow function (FOIS) and tube removal post therapy
Martin-Harris 2015 [216]	Airflow and inductance plethysmography	30	Swallows on expiration	H&N Ca	60 mins	2 x week	up to 4 weeks	Improvement in swallow breathing coordination, aspiration (PAS) and MBS Imp sub scores post therapy (no meaningful difference in swallow function/QOL (MD Anderson Dysphagia Inventory))
McCullough 2012 & 2013* [a] [141, 287]	sEMG	18	MM	stroke	45-60mins	2 x day	2 weeks	Improvement in hyoid displacement post therapy, no improvement in other physiological or functional measures. Cross over design – intervention vs no intervention
Reddy 2000 [269]	Accelerometry	5	SS, MM - with target	mixed	30 mins	1-3 x week	3-9 weeks	Subjective improvement in dysphagia severity on VFS pre therapy
Robbins 2007 [266]	Tongue manometry - IOPI	10	TS	stroke	no info	3 x day/3 days per week	8 weeks	Improvement in tongue strength and aspiration (PAS) post therapy but no or variable improvement in other physiological measures.
Steele 2012 [288]	sEMG	8	SS, ES & MM with targets	mixed	Unknown	Unknown	Unknown	Improvement on swallow strength (sEMG) post therapy variable improvement on physiological measures
Steele 2013 [274]	Tongue manometry - IOPI	6	TS and ES	Traumatic Brain Injury	no info	2 x week	11-12 weeks	Improvement in tongue strength and aspiration (PAS) post therapy but no or variable improvement in other subjective and physiological measures. Worsening of residue.
Steele 2016 [276]	Tongue manometry - IOPI	14	TS and ES	stroke	no info	2-3 x week	8-12 weeks	Improvement in tongue strength post therapy but no or variable improvement in other physiological measures pre and post therapy
Yeates 2008 [277]	Tongue manometry - IOPI	3	TS and ES	mixed	45 mins	2-3 x week	8-12 weeks	Improvement in tongue strength post therapy but variable improvement in other subjective and physiological measures

* included in meta-analysis; [a] same data presented in both studies; [†] abstract data only. MM = Mendelsohn manoeuvre; SS = saliva swallow; ES = effortful swallow; SGS = supraglottic swallow; SSGS = super supraglottic swallow; TS = tongue strength.

5.4.1.4 *Surface Electromyography (sEMG)*

Ten studies used sEMG as a means of providing biofeedback. sEMG measures the spatial and temporal properties of muscle action potentials. The amplitude of the signal increases with increased force of muscle contraction.[289] In nine of 10 studies, sEMG was used to measure the activity of the muscles which elevate and tilt the larynx during the pharyngeal swallow (the remaining study utilised sEMG in a patient with psychogenic dysphagia).[285] Two small electrodes are placed on the submental muscles (mylohyoid, geniohyoid, anterior belly of digastric and genioglossus) and a third reference electrode is usually placed to one side.[288] The sEMG signal represents the timing and force of the muscle contraction and is displayed graphically on a screen. sEMG has been employed using a variety of strategies, such as providing progressively more challenging targets based on strength and timing;[279] and enhancing the completion of a swallow protocol helping the participant with timing of muscle contraction and respiratory patterns.[283] The remaining studies used biofeedback to teach and practice either or both effortful swallow and the Mendelsohn manoeuvre (holding the larynx elevated for a target number of seconds).[141, 267, 280-282, 286, 288] Two studies met the criteria to be included in a meta-analysis. McCullough et al used sEMG biofeedback to teach and practice the Mendelsohn manoeuvre to patients who had dysphagia secondary to stroke. The data were reported in two papers,[141, 287] demonstrating significant improvements in duration of hyoid elevation ($p=0.011$) and anterior hyoid movement ($p=0.009$) but no other physiological or functional changes were found. Huimin et al provided swallow function training with biofeedback compared to swallow function training without biofeedback. They reported significant changes post intervention in the biofeedback group in upper oesophageal sphincter (UES) opening ($p=0.001$), pharyngeal transit time (PTT) ($p=0.038$) and maximum hyoid displacement ($p=0.033$).[265] Although in the remaining eight

studies design quality was poor, significant improvements were reported in functional and physiological swallowing measures.

5.4.1.5 Videoendoscopy

One study used videoendoscopy as a means of biofeedback.[284] This involves the insertion of a flexible nasoendoscope to the level of the soft palate so that the pharynx and larynx can be visualised. The timing, safety and efficiency of the swallow can also be visualised and used for biofeedback. Denk et al taught patients to employ swallowing manoeuvres and changes in posture using videoendoscopy for direct visual biofeedback. The manoeuvres included effortful swallow, Mendelsohn manoeuvre, supraglottic swallow and supra-supra glottic swallow depending on the nature of each participant's dysphagia. This study met the criteria for inclusion in a meta-analysis. The control group received the same intensity of therapy and exercise type without the biofeedback. All participants were tube fed initially and 73% of patients achieved therapeutic success, defined as tube removal and full and unrestricted oral intake. At 40 days, significantly more of the biofeedback group had achieved therapeutic success (p=0.041) however there was no significant difference between the intervention and control groups at six months.

5.4.1.6 Respiratory plethysmography

One study used respiratory inductance plethysmography and nasal airflow as a method of biofeedback to train participants to adopt a natural respiration/swallow pattern.[216] Nasal airflow is measured by a nasal cannula and respiratory inductance plethysmography measures movements of the ribcage and abdomen. These devices were attached to a Kay Pentax Digital Swallowing Workstation via Swallow Signals Lab which processed the signals

and presented the respiration patterns on a screen for the patients to use as feedback. They went through identification, acquisition and mastery stages to learn to swallow mid expiration with a mid to low lung volume and exhale post swallow. Significant improvements were reported with swallow physiological measures and swallow respiratory patterns but the there was no control group to compare outcomes.

5.4.2 Quantitative synthesis

Five studies had a non-confounded control group and thus met the criteria for inclusion in the meta-analysis (N=138).[141, 265, 272, 275, 284] Two were excluded because two different interventions were compared.[276, 282] The remaining 18 were excluded because they did not include a control group nor did they demonstrate an observational study design of sufficient quality. Study quality was variable (Table 5.2) with at least one element of bias evident in all of the studies.

Table 5-2 Risk of bias in the studies included in the meta-analysis.

Study	Suitable control	Random sequence generation	Allocation concealment	Blinding of participants /therapists	Blinding of assessors	Incomplete data	Selective reporting
Aoki 2015 [275]	+	-	Unknown	+	+	+	+
Denk 1997 [284]	+	Unknown	Unknown	-	-	-	-
Li 2016 [272]	+	-	-	-	-	+	+
McCullough 2012 & 2013 [141]	+	+	-	-	+	+	-
Huimin 2015 [265]	+	+	Unknown	Unknown	Unknown	Unknown	Unknown

+ = low risk of bias/good quality, - = high risk of bias/poor quality

Due to the range of outcome measures used, data from only three outcomes could be synthesized. Biofeedback did not improve swallow function (FOIS, t=2, n=51, MD=1.10; 95% CI [-1.69, 3.89], Figure 5.3 A); or clinical outcome (feeding tube removal, t=2, n=53, OR =3.19; 95% CI [0.16, 62.72], Figure 5.3 B). Biofeedback intervention had a significant positive effect on swallow physiology, specifically hyoid displacement (t=3, n=90, MD=0.22; 95% CI [0.04, 0.40], Figure 5.3 C); two of these studies used sEMG and one used accelerometry (Table 5.1). There was significant statistical heterogeneity between trials in measures of swallow function and number tube fed (I^2 = 70-94%) and low in physiological measures (I^2 = 8%). Sub-group analyses were planned to explore effects of biofeedback type, aetiology of dysphagia, setting and dose, including assessment for publication bias, but this could not be performed due to the paucity of studies.

5.5 Discussion

There is an absence of good quality, large-scale RCTs assessing biofeedback as an adjunct to therapy for dysphagia in adults. Meta-analysis of controlled studies showed a positive effect of biofeedback on one swallow physiology outcome; maximum displacement of the hyoid bone. No conclusions can be drawn from other positive results in functional, physiological and clinical outcome measures reported in several small, non-randomised controlled trials.

Three controlled trials found that biofeedback-augmented dysphagia therapy resulted in increased hyoid displacement [265, 272, 287] when compared to a control. Two of these studies used sEMG and the other used accelerometry for biofeedback, both of which show patients a representation of hyolaryngeal elevation. Studies with healthy subjects have demonstrated that increases in sEMG amplitude correlate with onset and offset of hyoid [290]

and laryngeal elevation.[291] The sEMG signal represents activity predominantly from mylohyoid, anterior belly of the digastric, and the geniohyoid muscles, confirmed using intra-muscular EMG.[292] sEMG amplitude increases with effortful swallowing [163] and the peak accelerometry signal correlates with peak laryngeal elevation.[293]

Biofeedback is used with the aim of improving timing, strength and duration of hyolaryngeal elevation. Therefore, it stands to reason that therapy targeting hyolaryngeal elevation results in corresponding physiological changes in hyoid displacement. Li et al reported functional changes in swallowing in their accelerometry study but unfortunately the other two studies did not report any data on functional outcome. Whether physiological change results in improvements in functional swallowing remains unclear. Three trials (using tongue manometry, [275] accelerometry [272] and videoendoscopy [284]) reported improvement in swallow function [272, 275] and tube removal post biofeedback intervention.[272, 284] However, when pooled in the meta-analysis these became neutral and non-significant.

These results need to be interpreted with caution since different types of biofeedback were used across studies and so heterogeneity was high. Included studies were also limited by both trial design and small sample size. For example McCullough et al used a cross over design in a heterogeneous population, a mix of subacute and chronic stroke participants, which will naturally recover at different rates.[287] In addition, they did not report the time allowed for treatment wash-out (if one exists) or any data in the crossover period, hence both treatment and 'control' groups received the intervention. Aoki and colleagues also had unmatched groups at baseline with more severe dysphagia in the intervention group, further confounding interpretation.[275] The causes of dysphagia in this trial were also mixed, hence understanding the results must be put into context of aetiology and the potential variation in response to treatment.

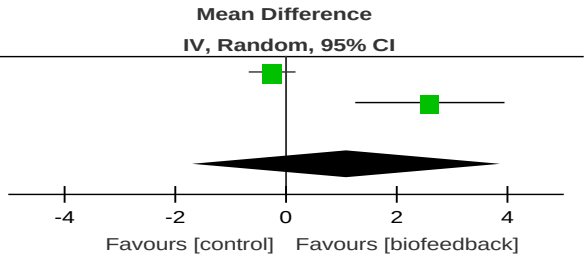
Figure 5-3. Results from Meta-analysis (Review Manager 5.3) showing changes in A) function, B) clinical outcome and C) physiology in patients receiving swallowing therapy with biofeedback compared to usual care.

A) Functional Oral Intake Scale (FOIS)

	Experimental			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Aoki 2015	4.75	0.77	17	5	0.33	14	52.6%	-0.25 [-0.65, 0.15]
Li 2016	5.1	1.2	10	2.5	1.78	10	47.4%	2.60 [1.27, 3.93]
Total (95% CI)			**27**			**24**	**100.0%**	**1.10 [-1.69, 3.89]**

Heterogeneity: Tau² = 3.81; Chi² = 16.13, df = 1 (P < 0.0001); I² = 94%

Test for overall effect: Z = 0.77 (P = 0.44)

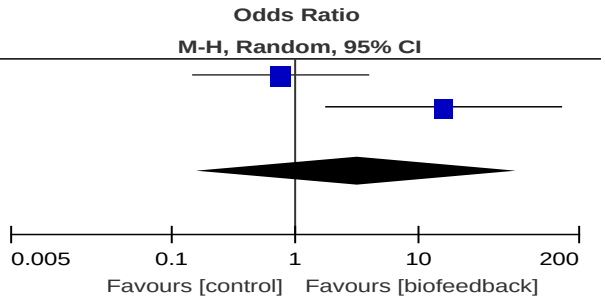


B) Numbers with feeding tube removed

	Experimental		Control			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI
Denk 1997	14	19	11	14	53.0%	0.76 [0.15, 3.92]
Li 2016	8	10	2	10	47.0%	16.00 [1.79, 143.15]
Total (95% CI)		**29**		**24**	**100.0%**	**3.19 [0.16, 62.72]**
Total events	22		13			

Heterogeneity: Tau² = 3.66; Chi² = 4.76, df = 1 (P = 0.03); I² = 79%

Test for overall effect: Z = 0.76 (P = 0.45)

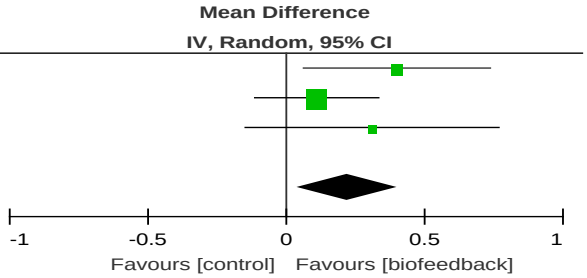


C) Hyoid displacement (cm)

	Biofeedback			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Huimin 2015	1.3	0.6	17	0.9	0.4	19	27.5%	0.40 [0.06, 0.74]
Li 2016	1.45	0.26	10	1.34	0.25	10	57.1%	0.11 [-0.11, 0.33]
McCullough 2012 & 2013	1.99	0.72	17	1.68	0.64	17	15.4%	0.31 [-0.15, 0.77]
Total (95% CI)			**44**			**46**	**100.0%**	**0.22 [0.04, 0.40]**

Heterogeneity: Tau² = 0.00; Chi² = 2.17, df = 2 (P = 0.34); I² = 8%

Test for overall effect: Z = 2.35 (P = 0.02)



Biofeedback might enhance recovery and improve aspiration risk in the short-term but may not lead to significant gains in the long-term. In patients with head and neck cancer, Denk reported a significant difference in means between groups at 40 days but not at the end of the study (6 months).[284] The authors suggest that biofeedback helps patients learn manoeuvres and exercises but once learnt, the biofeedback has no benefit. If so, these early gains could be beneficial for those with dysphagia secondary to multiple causes – it may mean quicker return to full normal intake, improve a patient's quality of life, reduce morbidity, length of stay in hospital and health costs. Whether biofeedback for dysphagia is beneficial or not in both the short and long term needs further investigation.

Across all the biofeedback intervention studies included in the qualitative analysis, heterogeneity in method and therapy exercise was observed, hence it is important to use appropriate outcome measures depending on the mechanism targeted. Accelerometry and sEMG biofeedback enables a representation of the strength and duration of hyolaryngeal elevation; six of 15 studies aimed to increase hyolaryngeal elevation[265, 269, 270, 272, 287, 288] but only four measured this as an outcome.[265, 272, 287, 288] The remaining studies aimed to improve swallowing skill and measured function or overall severity. Tongue manometry aims to improve lingual strength and timing; four of five studies [274, 276, 277, 294] measured this and oral control appropriately as an outcome. The study utilising respiratory plethysmography measured coordination of breathing and swallowing which is the mechanism it was targeting in therapy.[216] Videoendoscopy enabled feedback should measure changes in swallow safety and efficiency and physiological changes dependent on the strategies learnt i.e. Mendelson manoeuvre targets hyolaryngeal elevation. However, in the included study only 'therapeutic success' (defined as tube removal and return to full oral diet) was measured.[284]

Biofeedback is often used in physiotherapy to augment skill based therapy and skill training results in better functional outcomes than non-specific strength training in adults post stroke [52]. All but one of the studies included in the qualitative synthesis used the task of swallowing as either the target exercise or one of the exercises within the therapy sessions. This involved exercises and strategies to improve the strength, timing and/or duration of the swallow. Further work is needed to determine whether biofeedback paired with swallow skill vs strength training results in better outcomes.

It is not known if biofeedback may be better focussed on specific types of dysphagia, or whether it can be applied more generally. In the present review, only four studies included patients with a specific type of impairment that the biofeedback targeted, none of which were included in the meta-analysis. Three tongue manometry studies included patients if they had poor oral control and/or reduced lingual strength.[276, 277, 294] One of the sEMG studies included patients only if they had evidence of reduced hyolaryngeal excursion.[288] The remainder included patients with any type of swallowing impairment or any type of pharyngeal dysphagia. The diverse range of methods used with biofeedback provides a challenge in selecting the most appropriate technique for future studies. This will also depend on the expected natural progression of the underlying cause of dysphagia in the population studied. Defining the nature of the swallowing impairment in future studies will help to identify which patients might benefit from specific forms of biofeedback.

Due to the paucity of studies, subgroup analysis was not possible to investigate whether one type of biofeedback was more efficacious over others, whether specific impairments respond better to biofeedback, or the optimal dose of therapy relative to outcomes, and timing of intervention. Therefore, there is insufficient evidence to guide clinicians in the use of biofeedback and its use will be dependent on the local resource.

5.5.1 Study Limitations

Several limitations should be considered when interpreting our results. Selection bias may be present but this risk was minimised by searching a range of databases and grey literature, and using two reviewers to search and select appropriate publications. Authors were contacted when information was not available in the text, although there was a limited response to these requests. Only English language studies were included which increases a risk of bias towards publications in larger English language international journals, which possibly tend towards studies with positive results. One Chinese article with sufficient detail in an English abstract was included despite no access to the full text.[265] However, there were limited methodological details available such as the means of measuring hyoid elevation and thus it was impossible to assess its full risk of bias and quality. A second limitation in interpreting this review is the paucity of good quality RCTs with blinding and transparent reporting of data. Most of the studies identified were single case studies or small studies with no control groups. There is also an absence of good quality observational or longitudinal studies that use pre-interventional measures as a comparator. This review was purposely broad on the inclusion of studies in the meta-analysis because there are so few. It would be easy to exclude all of them on the basis of quality. Heterogeneity was also evident across the studies, including statistical heterogeneity. Although statistical heterogeneity was low in the physiological measures it should be interpreted in the context that methods varied considerably across studies. Therefore, the outcomes must be interpreted with caution. For example two of the five studies in the meta- analysis had a control group that did not receive exactly the same intervention [275, 287]. The control groups in the remaining three studies received the same type and intensity of exercise – the only difference being biofeedback [265, 272, 284]. Thus, the meta-analysis may not solely tell us about the augmentative effects of biofeedback per se

but the effects of biofeedback paired with a variety of exercises. Third, the variety of outcome measures limited the amount of data that could be pooled in meta-analyses. Also, some studies reported only outcomes in swallow physiology or performance on a target exercise but these do not necessarily signify meaningful change for patients.

5.5.2 Conclusions

Dysphagia therapy augmented by biofeedback seems to improve physiological outcome, specifically hyoid displacement, but whether this translates to functional improvements is not clear. However, data obtained from small studies at high risk of bias and conclusions must be interpreted with caution. Further good quality research is required to guide whether biofeedback-augmented dysphagia therapy leads to better outcomes for patients with dysphagia. Particular attention should address specific populations (aetiology and dysphagia type) with clearly defined timing of administration relative to the onset of dysphagia. Further, the dose of swallow therapy (number, length and intensity of sessions) paired with biofeedback is unknown and should be assessed using well-designed, randomised controlled trials. Further research is also needed establishing validated and meaningful outcome measures following swallow therapy.

Chapter 6: A randomised controlled feasibility study of strength and skill swallowing training with surface electromyographic biofeedback in acute stroke

Conference presentation arising from this chapter:

- European Society for Swallowing Disorders Conference 2018 Poster presentation for ongoing study.
- UK Stroke Forum 2018 Poster presentations for ongoing study.

Contributions:

The author collated the majority of the data, analysed and interpreted the data and wrote the chapter. Amanda Hedstrom collected 90-day data. Lisa Everton analysed 10% of the videofluoroscopy data for reliability.

6.1 Introduction

The systematic review in Chapter 5 demonstrated paucity of evidence and lack of clarity over which biofeedback methodology is superior. However, the findings can contribute to the current literature to help to design future research studies. The systematic review confirmed that sEMG was the most common biofeedback instrument in published studies and given it is a cheap, readily available tool that clinicians can access, this was the instrument used in this next phase of the study.

The meta-analysis showed that sEMG and accelerometry paired with one or more of swallow skill, effortful swallow and Mendelsohn manoeuvre exercise may improve hyolaryngeal elevation compared to no-biofeedback or no therapy. Functional skill-based training compared to non-task specific strength training has been shown to increase neuroplasticity and improve functional outcomes in post stroke motor rehabilitation studies [50, 51, 295]. Functional swallow skill training involves repetitive swallowing with differing means of providing progressive challenge such as using bolus volume and viscosity [282], timing and strength targets [279] or strength targets alone [283, 286]. The effortful swallow (ES) is an example of skill training with strength targets [296]. Patients with post stroke dysphagia are able to perform effortful swallows [297].

Furthermore, interventions that are intensive, repetitive, salient, task specific and progressively challenging are likely to optimise neuroplasticity [45, 46]. The Biofeedback in Strength and Skill Training (BiSSkiT) software paired with submental sEMG can give users visual feedback on the amplitude (strength training) and amplitude and timing (skill training) of their swallow and sets progressively more challenging targets based on user performance[298]. Only one other software tool, the Silverfit Rephagia system, was found to

be commercially available that can offer skill and strength training with the progressive challenge the BiSSkiT offers. It also has a superior game-like graphical interface. However, at a significantly higher cost, it was not within the budget for this study.

The dose of intervention given by the three studies that demonstrated favourable results in the systematic review was moderately intensive, 45–60-minute sessions, totalling 15 – 24 sessions over 2-6 weeks. Previous strength and skill training with sEMG biofeedback studies have recruited patients with chronic dysphagia but neuroplasticity may be optimised in the early weeks post stroke [44]. Therefore, offering therapy at an acute stage may result in better outcomes. Additionally in the inpatient setting providing intensive therapy may be more feasible given that on average, most patients are only seen once per week in community settings [299]. Patients with dysphagia on an acute stroke hospital ward reported that using sEMG with biofeedback to perform the effortful swallow was comfortable and they would consider it acceptable as part of regular therapy [297]. Given, average inpatient stay following stroke is 18 days and based on the results from the systematic review it was decided to offer a moderately intensive therapy over a shorter period; 45-minute sessions, five days a week over two weeks. Little is known whether it is feasible to deliver this intervention in an acute stroke setting, whether patients at this stage of their recovery can tolerate it and whether it results in better outcomes for those patients compared to their usual care.

6.2 Aims

The objective of this prospective, randomised, controlled feasibility study was to investigate whether sEMG biofeedback paired with swallow strength and skill training is feasible and acceptable in the acute stroke setting. Its effects on swallow function, swallow physiology, and clinical outcomes to inform a larger study assessing effectiveness of the intervention were

assessed. The aim was to determine an achievable rate of recruitment, verify randomisation and assessment procedures, select the most suitable outcome measures; and calculate the sample size for a larger trial.

6.3 Methods

6.3.1 Participants

Participants were recruited consecutively from the acute stroke and rehabilitation wards at Royal Derby Hospital over a 24-month period. They were eligible if they had a clinical diagnosis of a new stroke within four weeks, were >18 years old, had new dysphagia with Functional Oral Intake Score (FOIS) (Appendix 15) ≤5[300].

Exclusion criteria included previous dysphagia, being medically unwell, poor medical prognosis, diagnosis of a progressive neurological disorder, severe cognitive, communication or visual impairment, inability to access videofluoroscopy (VFS) assessment and pregnancy. Severe visual impairment was defined by those with identified visual or spatial inattention impairments and who were unable to trace a pattern on a page with their finger. Only participants with capacity to consent were recruited to the study and written consent was obtained from all the participants (Appendix 17), this also served to exclude patients with severe cognitive or communication impairment. Participants were provided with written information sheets and an aphasia friendly version was created to support those with communication and cognitive impairments. (Appendix 16). The Stroke Persons Involvement Group (SPIG) at Derby reviewed the information sheets and gave readability feedback which was used to improve them.

6.3.2 Ethics and approvals

The study received a favourable opinion from the South Central - Oxford C Research Ethics Committee REC ref: 17/SC/0272). The trial was registered at Clinical Trials.gov (NCT03499574). The protocol and statistical analysis plan were published prior to recruitment completion [301].

6.3.3 Randomisation and blinding

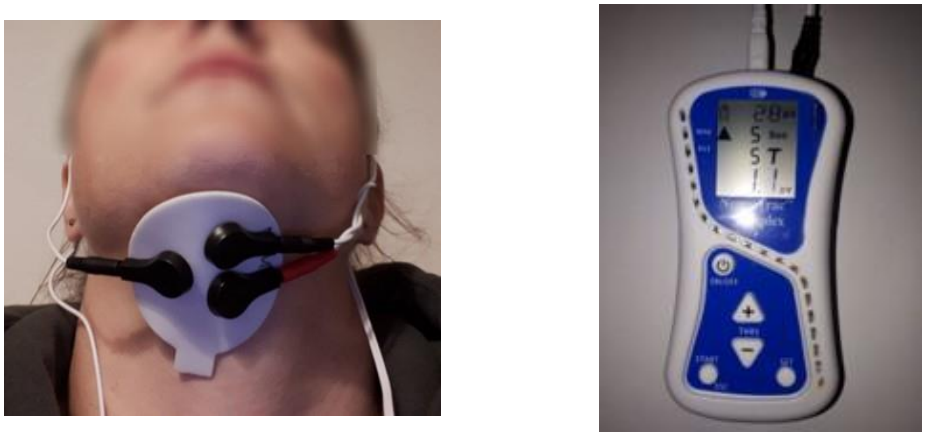
Once the patient consented and baseline data collection was complete, information regarding the patient's age, swallow function (FOIS) and stroke severity (National Institute of Health Stroke Severity – NIHSS) (Appendix 18) were given to the trial office and allocation to either of the groups was computed using minimisation with a 25% random element. Randomisation with minimisation was chosen to try to match groups so that differences could be attributed to intervention rather than group differences [302]. Dysphagia severity was the main secondary outcome therefore baseline swallow function was important to control. Stroke severity also impacts on long- and short-term outcomes and older people have less propensity to neuroplasticity than younger patients. Clinicians and researchers conducting and analysing the VFS were blinded to treatment group as was the researcher conducting the 90-day follow ups. The researcher collecting two-week outcome measures was not blinded to treatment group.

6.3.4 Intervention

In addition to usual care, the treatment group received up to 10 sessions of 1:1 therapy over a two-week period carried out by JB. Sessions lasted up to 45 minutes as tolerated. Therapy was given at bedside or in a therapy room on the stroke ward. A triode electrode was placed

under participants' chins, with the two main electrodes aligned along the submental muscles and the reference electrode to one side as has previously been reported[288]. Figure 6.1.A

Figure 6-1 A. Placement of electrodes along submental muscles for sEMG biofeedback. B. Neurotrac Simplex sEMG device.

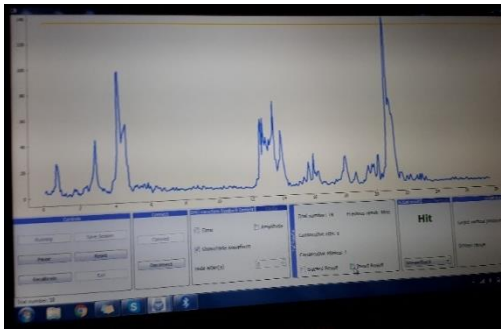


These were connected to a laptop via a surface electromyography device. The Neurotrac Simplex device used in this study has been CE0088 marked for use as a surface electromyography tool for biofeedback Figure 6.1 B.

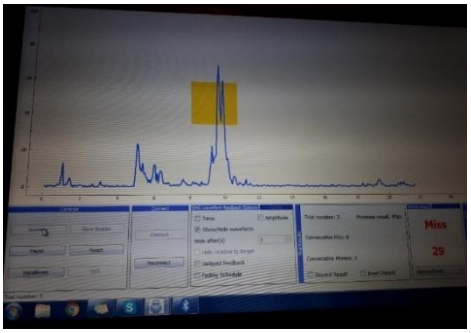
The BiSSkiT software (University of Canterbury, New Zealand) allowed participants to visualise the timing and amplitude of their submental muscle activity on the screen and use this biofeedback in the strength and skill training exercises. After calibration to the individual, strength training required participants to swallow at a target amplitude set at 70% of their maximum average effortful swallow Figure 6.2.A. Skill training required participants to hit an amplitude and timing target with their swallow which changed on each trial Figure 6.2.B. The targets became more or less challenging as they hit or missed the targets.

Figure 6-2 A. BiSSkiT Strength training paradigm B. BiSSkiT Skill training paradigm

A.



B.



Participants completed one swallow per 30 seconds in up to three strength blocks and three skill blocks of 10 trials each with a rest between blocks. Appendix 19 shows the session protocol. If participants were unable to complete the skill blocks, they continued with the strength training.

6.3.5 Usual care

Usual care routinely consisted of swallow reviews, liaison with the multidisciplinary team, patient and family education and swallow therapy by the usual ward based clinical SLTs.

6.3.6 Outcomes

6.3.6.1 Primary Outcome

Feasibility was measured by the number of participants recruited, the number of sessions completed and the length of sessions tolerated. Data were collected during the intervention period. To determine feasibility the following criteria had to be met 1. Recruitment of planned 30 participants 2. Compliance rate of 80% or over meaning 80% of participants had to complete 80% of sessions. Acceptability of the intervention was measured using a feedback questionnaire at the end of the intervention with those in the treatment group.

6.3.6.2 Secondary Outcomes

These were gathered at baseline, two weeks and at a selection at 90 days. Table 6.1.

Clinical and safety outcomes

Stroke severity was measured using the NIHSS (Appendix 18), a standardised neurological assessment tool used clinically globally to measure stroke severity. It has demonstrated acceptable validity and high inter-rater reliability with training [303].

Disability was measured using the 7 point modified Rankin Scale (mRS) from 0= no disability to 6 = dead (Appendix 20) [304]. Dependency was measured using the Barthel Index (BI) (Appendix 21) with 0 = total dependence and up to 100 = independence [305]. Both measures are commonly used in stroke trials. Depression was measured using the Signs of Depression Scale (SDSS) (Appendix 22) which has been found to be sensitive and specific in identifying depression in elderly medically unwell patients, although it is not specific to stroke it is a short and simple observational tool that was scored routinely as part of usual care at RDH. A cut off of ≥ 3 points indicates possible depression [306]). Death, pneumonia and length of stay in hospital were also measured. Pneumonia was defined by (a)Patient's temperature is at least 37·5°C or higher on two consecutive measurements or one measurement of 38·0°C or higher and (b) a respiratory rate of 20 breaths per min or more, or cough and breathlessness, or purulent sputum, and (c) a white blood cell count that is higher than 11·0×109/L, or chest infiltrates on radiograph, or positive sputum culture or microbiology, or positive blood culture [307]. Lower respiratory tract infection (LRTI) was defined as patients being treated with antibiotics for chest infection or pneumonia but didn't meet criteria for pneumonia.

Table 6-1 Timescales of secondary outcome measures

	Timepoint		
Measure	Baseline	Post intervention (2weeks)	Follow up (90 days)
Oral intake (DTNAx)	X	X	
Swallow function (FOIS)	X	X	X
Swallow severity (DSRS)	X	X	X
Swallow physiology (VFS – timing measures)	X	X	
Swallow safety (VFS - PAS)	X	X	
Swallow efficiency (VFS – MBS-ImP)	X	X	
Quality of Life (DHI)	X	X	X
Stroke Severity (NIHSS)	X	X	X
Disability (BI)	X	X	X
Impairment (mRS)	X	X	X
Depression (SDSS)	X	X	X
Pneumonia	X	X	X
LOS			X
Death		X	X

Swallow function outcomes

Swallow function was assessed using the FOIS (Appendix 15) this is a 7-point scale that measures oral intake from 1 = no oral intake with tube feeding up to 7 = Normal dietary intake, the scores 4-7 are scored only for diet intake rather than fluids. It was chosen as an outcome measure because it is one of the most commonly used scales in dysphagia that has undergone validation in stroke patients demonstrating adequate interrater reliability, consensual and criterion validity and cross-validation with other swallowing measures [300].

Swallow severity was assessed using the Dysphagia Severity Rating Scale (DSRS) (Appendix 9). This is a 13-point scale evaluating fluid and diet intake and amount of supervision required. A score of 0 = no dysphagia and up to 12 = most severe dysphagia, where patients are unable to manage any oral intake and they are dependent on tube feeding. The tool has recently undergone thorough validation, demonstrating moderate to excellent concurrent and

predictive criterion validity, internal consistency, inter- and intra-rater reliability and sensitivity to change [225].

A comprehensive swallow screening assessment was also carried out, the DTNAx (Appendix 1), described and validated in Chapter 3. A score was assigned to the diet and fluid outcome of the DTNAx (Table 6.2) to make comparisons simpler. Table 6.3 shows how the DTN maps over to the FOIS and DSRS. This is not a perfect mapping as the DTNAx does not test all textures, allow for diet or fluid trials, or does not account for supervision but it does demonstrate that as the scores increase on the DTNAx they appropriately increase on the DSRS and decrease on the FOIS.

Table 6-2 Outcome of the DTNAx scoring

Fluids	Score
L0	0
L2	1
L3	2
NBM	3
Diet	Score
L7	0
L6	1
L5	2
L4	3
NBM	4
Total score	7

Table 6-3 Possible outcomes from DTNAx compared to the FOIS and DSRS

Fluids	Diet	Total DTNAx score	FOIS equivalent	DSRS equivalent (diet and fluids only sections)
L0 = 0	L7 = 0	0	7	0
L0 = 0	L6 = 1	1	5	2
L2 = 1	L7 = 0	1	6	2
L0 = 0	L5 = 2	2	4	3
L2 = 1	L6 = 1	2	5	3
L3 = 2	L7 = 0	2	6	3
L0 = 0	L4 = 3	3	4	3
L2 = 1	L5 = 2	3	4	4
L3 = 2	L6 = 1	3	5	4
L0 = 0	NBM = 4	4	3	4
L2 = 1	L4 = 3	4	4	4
L3 = 2	L5 = 2	4	4	5
NBM = 3	L6 = 1	4	3	6
L2 = 1	NBM = 4	5	3	5
L3 = 2	L4 = 3	5	4	5
NBM = 3	L5 = 2	5	3	7
L3 = 2	NBM = 4	6	3	6
NBM = 3	L4 = 3	6	3	7
NBM = 3	NBM = 4	7	0	8

Quality of life with regards to swallowing was assessed using the Dysphagia Handicap Index (DHI) (Appendix 23). This index involves a series of 25 statements around the physical, functional and emotional aspects of dysphagia an example statement is 'I avoid eating because of my swallowing problem'. Participants are required to answer never, sometimes or always with regards how often each statement applies to them. It scored 0 = never, 2 = sometimes and 4 = always with a minimum score of 0 signifying no QOL issues and a maximum score of 100 for the poorest quality of life. It also involves a self-rating of swallow severity from 0-7 with 7 as the most severe swallowing difficulty. The DHI has undergone a degree of validation with mild to moderate dysphagic patients including an unspecified number of stroke patients. It was found to differentiate between controls and those with dysphagia, has

high internal validity and test–retest reliability, and is sensitive to significant differences in severity of dysphagia [308].

Swallow physiology outcomes

VFS was carried out in the hospital clinic by a speech and language therapist (SLT) and radiographer and or radiologist. The VFS were anonymised and later analysed by blinded trained experienced VFS clinician. A further 10% were analysed by a second blinded trained experienced VFS clinician. In each VFS participants were given four 5ml sips of thin barium (International Dysphagia Diet Standardisation Initiative (IDDSI) Level 0 – L0), 1 x 50ml drink of IDDSI L0 thin barium and two 5ml teaspoons of IDDSI level 4 puree diet. Including greater than three boluses with fluids is important to accommodate variability in swallowing [109]. A larger volume of fluids is more challenging and likely to demonstrate impairment [309]. Efficiency and clearance may be better measured with diet textures thus puree consistency boluses were included. Baritop 100 was used as the contrast and was diluted to a 40% volume to volume to ensure accuracy of VFS interpretation [204]. Continuous images were recorded onto DVD with a Phillips system at the maximum possible frame rate with the equipment available of 25fps. This was to ensure that as much detail was possible for interpretation, less frames may result in different scores for MBSImP, PAS and timing measures [208] VFS were analysed using Kinovea Version 0.8.15. See Chapter 3 for more details regarding process and rational for VFS set up.

VFS was used to measure swallow physiology (timing and displacement measures), safety (Penetration Aspiration Scale (PAS) [215]) and efficiency (selected components from the Modified Barium Swallow Impairment profile (MBS-ImP) [122]). See table 6.4 with a summary of the analyses and Appendix 24 for a description of the measures. The set of timing and efficiency measures used and decisions for boluses analysed is based on work by Everton et

al 2020 [310]. Everton et al developed a set of operational rules to accompany the timing measures. Both the VFS analysts trained using the rules to improve accuracy and reliability of the measures.

One of the hypothesised mechanisms behind how biofeedback with submental sEMG improves swallowing is with increased hyoid displacement. Methods for measuring hyoid displacement were considered. A standard plane, a calibrated measure, anatomical reference points, defined resting and maximum displacement frames and defined area of the hyoid are all important in calculating displacement. Displacement measures from different studies cannot be compared if their methodology is different[311].

A scaled or distance measure is required to correct for image magnification. One method to measure distance of displacement is to use an external reference such as a coin or a marker of a defined size that measurements can be calibrated to [312-314]. Other methods include

Table 6-4 Videofluoroscopy outcome measures for the 5ml Level 0 fluids and 5ml Level 4 puree diet boluses.

Assessment domain	Swallow measure	Measurement process/tool	Boluses analysed
Safety	Aspiration	Penetration Aspiration Scale	Score per bolus – mean PAS of the four L0 boluses and PAS of the worst L4 bolus use in the analysis.
Physiology	Kinematics – timing measures	Global oral transit time (GOTT) (Everton 2020 unpublished)	**5ml Level 0 thin fluid** The physiology of the boluses with the Worst, Mode and Best PAS scores were analysed. The mean of these three were reported. **5ml Level 4 puree diet** The physiology of the bolus with worst PAS score was analysed and reported.
		Stage transition duration (STD) [315]	
		Laryngeal vestibular closure (LVC) [316]	
		Laryngeal closure duration (LCD) [317]	
		Pharyngeal reaction time (PRT) [317]	
		Pharyngeal transit time (PTT) [144]	
		Maximum hyoid duration (MHD) [318]	
		Upper oesophageal sphincter closure duration (UESD) [144, 319]	
	Displacement	Anterior hyoid displacement (AHD) [320]	
		Superior hyoid displacement (SHD) [320]	
	Initiation of Pharyngeal Swallow (IPS)	Modified Barium Swallow Impairment Profile (MBS-ImP) [122] – component 6	As above for which boluses were analysed. Mean number of swallows was reported. Median scores reported for MBSImP measures.
Efficiency	Pharyngeal residue	MBS-ImP – component 16	
	Number of swallows	Per bolus	

using an anatomical scalar such as the height of C3 vertebrae [287] which is has been found to be approximately 15mm. Steele and colleagues argue that height and thus gender influences hyoid displacement therefore comparisons cannot be made unless this has been

controlled for. Instead, they suggest scaling each participant's hyoid displacement measurement to the distance between their C2 and C4. Using this method displacement is relative to size. As this study collected both baseline and follow up data on hyoid displacement a marker was used rather than a scaler because when comparing changes over time between two groups for example raw data can be analysed using analysis of covariance (or ANCOVA) or multiple regression. Here the variation in baseline values is taken into account when comparing groups. In this study the marker used was a five pence piece which measures 18mm long and was secured with surgical tape to each participant's chin. This could be used to calibrate the ruler on the Kinovea software.

A reference plane is required to control for head position and movements within and between subject. Additionally, in order to measure movements of the hyoid, reference planes need to be used to define the direction of anterior and superior movements. Hyoid position has strong linear correlations with head, jaw and C1-C4 vertebrae [321]. Camper's plane was found to be the plane demonstrating the most consistent relationship across ages between hyoid displacement and diameter of UES opening when compared to other cervical spine planes[314]. C2-C4, C2-C5 and C3-C5 planes were compared, there was an average of 0.01cm difference in anterior displacement between the measures but this was greater up to 0.2cm difference for superior displacement. Zu et al 2011 also found that measuring hyoid in C2-C4 and C2-C5 planes resulted in different values[311] suggesting that data from studies with different methodology cannot be compared[314]. The differences may be related to spine changes in older adults which alter the angle of a plane measured along the cervical spine. In some studies, instead of defining a particular plane and its perpendicular as axes, hyoid displacement is measured in relation to a reference point or anchor. The distance from max displacement of hyoid to the anchor minus the distance from resting hyoid to anchor

constitutes displacement [312, 313] which incorporates both anterior and superior movements. Normative data needs to be derived for each of the planes or a standard plane needs to be agreed for research. It may be that either C2-C4, which is one of the most commonly used planes [322] (and requires no use of external markers that are difficult to find) or Nakane's plane are good candidates for a standard. Due to the ease of use and with it being the most common plane in research the C2-C4 plane was used in this study as per Sia et al 2012.

The point on the hyoid that is to be measured also needs to be defined. This varies between studies but is usually the anterior superior or anterior inferior point of the hyoid. Similarly, the points of reference on which the plane of choice is based need to be defined i.e. anterior inferior corner of C2 and C4. The anterior inferior corner of both hyoid and cervical vertebrae was used in this study.

In order to measure displacement a starting point needs to be determined. In previous studies definitions of resting hyoid frame vary [322]. This frame has been taken as the lowest position, at a defined frame before swallowing, such as the frame before hyoid or laryngeal excursion [323] or in relation to bolus location such as during bolus hold prior to swallowing [312, 313]. It has to be noted that prior to the superior and anterior movements the hyoid may dip inferiorly. If this frame is taken it may exaggerate the displacement of the hyoid. Therefore, the frame prior to bolus transfer from the oral cavity was taken to avoid this. Maximum displacement can be defined as the frame showing the most superior and anterior position of the hyoid or the maximum anterior position and the maximum superior position can be treated separately. In this study they were taken separately to explore the effect of the intervention.

The method decided upon for determining anterior and superior hyoid displacement in this study was adapted from the methodology of Sia et al 2012 [320] for use with the Kinovea software Version 0.8.15. Appendix 25 details the steps involved to take the measurements.

6.3.7 Sample size

A pragmatic target sample size of 30 was agreed based on likely number of eligible patients, researcher time and access to radiological assessments. With a sample size of 14-15 (treatment group) an 80% compliance rate to within a 95% confidence interval of +/- 20% was estimated. Recruitment was reviewed midway and the target was lowered to 27 as recruitment rate was slower than predicted.

6.3.8 Statistical analysis

For feasibility and acceptability outcomes, descriptive statistics were generated. Normally distributed data are presented as means ±SDs; non-normally distributed data as medians (interquartile ranges) and categorical data as numbers (percentages).

Outcomes of the treatment group were compared to the control group using binary or ordinal logistic regression for categorical variables and multiple linear regression for continuous variables. Statistical adjustment was made for randomisation by minimalization on stroke severity (NIHSS) and swallow function (FOIS). Mean change in swallowing outcomes from baseline to post intervention was explored across groups and baseline measures were used as covariates to compare biofeedback and control groups post intervention.

Inter and intra- rater reliability VFS data were analysed using intra-class correlation coefficient for continuous data, kappa for dichotomised data and weighted kappa for ordinal data. These were calculated for individual timing frames i.e. frame when hyoid at height of elevation,

rather than composite scores i.e. Hyoid elevation duration = frame hyoid starts to descend - frame hyoid at height of elevation. It is often unclear in published manuscripts on the exact methods in this much detail used to explore reliability, however this is the method reported by Steele et al 2019 [109].

6.4 Results

6.4.1 Baseline data

Twenty-seven participants were recruited with mean age 73.3 (11.0), 19 females (70.4%) and 21 had an ischemic stroke (77.8%). Despite minimalizing for stroke severity, the Biofeedback group had mean NIHSS significantly greater (13.4 vs 8.7, p=0.023) than the control group. The Biofeedback group also demonstrated greater disability and dependency. Mean time to randomisation was 22.4 days (SD 9.5) and participants were recruited later to the Biofeedback group. The groups were well matched on the swallowing measures. Table 6.5.

Two patients, one from each group died before 90 days. To reconcile this in data analysis, scores were assigned for the following measures: NIHSS = 43, mRS = 6, BI = -1, DSRS = 13, FOIS = 0, DHI = 101, SDSS = 7. NIHSS was not collected for one patient in each group at 90 days due to the need to conduct the data collection via telephone owing to COVID-19. At two weeks a small number of data were missing due to poor compliance with study procedures. One VFS data did not record due equipment malfunction, the same participant was discharged before two-week data collection. Numbers are highlighted on the results tables.

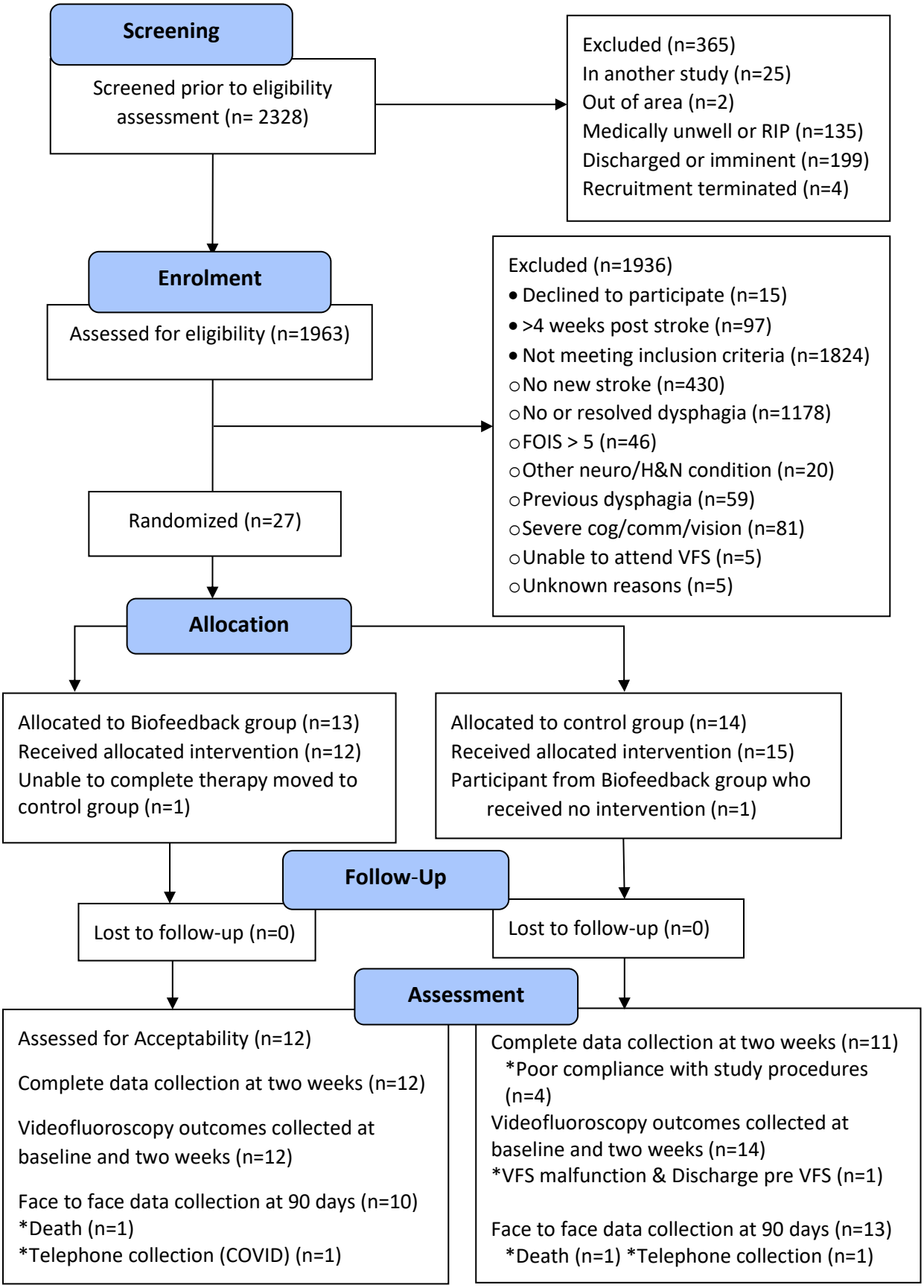
Table 6-5 Baseline data

Variable		Total n=27	Biofeedback n=12	Control n= 15
Age		73.3 (11.0)	71.0 (10.4)	75.1 (11.5)
Sex, female (%)		19 (70.4)	6 (50.0)	13 (86.7) *
Previous Stroke/TIA (%)		2 (7.4)	0 (0.0)	2 (13.3)
Pre morbid Modified Rankin Scale (/6)		0 [2]	0 [2]	0 [2]
Days to randomisation post stroke		22.4 (9.5)	27.4 (8.76)	18.3(8.2) *
Stroke type	Haemorrhagic	6 (22.2)	2 (16.7)	4 (26.7)
	Ischaemic	21 (77.8)	10 (83.3)	11 (73.3)
Stroke syndrome	TACS	15 (55.6)	9 (75.0)	6 (40.0)
	PACS	6 (22.2)	1 (8.3)	5 (33.3)
	POCS	2 (7.4)	1 (8.3)	1 (6.7)
	LACS	4 (14.8)	1 (8.3)	3 (20.0)
NIHSS (/42)		10.7 (5.1)	13.1 (4.93)	8.7 (4.4)*
Modified Rankin Score (/6)		4 [1]	5 [1]	4 [0] *
Barthel Index (/100)		18.7 (19.7)	10.8 (9.5)	25.0 (23.5)
Dysphagia severity rating scale (/12)		6.3 (2.1)	6.3 (1.9)	6.3 (2.4)
Functional oral intake scale (/7)		3 [1]	3 [1]	4 [1]
DTNAx score (/7)		3 [1]	3.5 [1]	3 [2]
Feeding route	Oral diet – normal	0 (0)	0 (0)	0 (0)
	Oral diet - modified	11 (4.07)	3 (25.0)	8 (53.3)
	NG feeding	16 (59.3)	9 (75.0)	7 (46.7)
	PEG feeding	0 (0)	0 (0)	0 (0)
	Other	0 (0)	0 (0)	0 (0)
Swallowing QOL (DHI) (n=26)		27.5 (17.9)	29.6 (20.1)	25.9 (16.7)
Mood (SDSS)		0 [2]	0.5 [1]	0 [2]
PAS 5ml thin fluids		2.9 (1.6)	3.2 (1.9)	2.6 (1.5)
PAS 50mls thin fluids (n=23)		4.3 (2.0)	4.0 (2.1)	4.7 (1.9)
PAS 5ml puree		1.5 (1.0)	1.4 (1.2)	1.6 (0.9)

Data are number (percentage), mean (standard deviation) or median [interquartile range].

* Independent t-test, Mann-Whitney U or Chi-squared test demonstrated significant differences between groups $p<0.05$

Figure 6-3 CONSORT Diagram



6.4.2 Feasibility & Acceptability

Of the 1,963 patients screened for eligibility, 1,824 did not meet the inclusion criteria and 97 passed the cut off of four weeks whilst waiting for researcher capacity to recruit them. Of the 42 participants who met the criteria and were approached, 15 declined and 27 consented to participate, with 13 participants randomised to the Biofeedback group. Figure 6.3 Consolidated Standards of Reporting Trials CONSORT diagram shows the recruitment, randomisation and retention of participants. One participant was unable to participate in any of the intervention sessions or the follow up direct outcome measures due to requests to stop shortly after consenting to the sessions. All of the remaining 12 in the Biofeedback group completed the intervention. (Table 6.6). A quarter (3/12) of patients' dysphagia resolved prior to completing 10 sessions and the remaining nine participants completed on average 8.7 sessions. This gives a compliance rate of 80% (95% CI 58%-100%). Sessions lasted an average of 36.2 minutes (sd 7.4) out of a total 45 minutes. There were no serious adverse events related to the intervention. Table 6.7 gives a breakdown of unrelated and improbably related serious adverse events and shows more recurrent respiratory tract infections in the control group than the biofeedback group.

Table 6-6 Feasibility data for the Biofeedback study

	Biofeedback
No. recruited	27
No. randomised to Biofeedback group	13
Patients that completed the intervention or resolved	12 (92.3%)
Mean no. of sessions completed per participant (/10)	8.7 (1.0)
Participants that completed eight or more sessions or resolved	11 (84.6%)
Mean length of session tolerated (max 45 mins)	36.2 (7.4)
No. of related serious adverse events	0

Data are number (%), mean (SD)

Table 6-7 Unrelated or improbable serious adverse events in the Biofeedback study

SAE – expected events	Total (n=27)	Biofeedback (n=12)	Control (n=15)
Total number of SAEs	20	6	14
Pneumonia	10 (50.0)	4 (66.7)	6 (42.9)
LRTI	5 (25.0)	1 (16.7)	4 (26.7)
AKI	1 (5.0)	0	1 (6.7)
Metastatic gastric cancer	1(5.0)	0	1 (6.7)
Ischemic colitis	1 (5.0)	0	1 (6.7)
Fall and Fracture	1 (5.0)	0	1 (6.7)
NSTEMI	1 (5.0)	1 (16.7)	0
Number of participants with SAEs	11 (40.7)	4 (33.3)	7 (46.7)
Relationship to intervention			
Not related	17 (85.0)	5 (83.3)	12 (85.7)
Improbably	3 (15.0)	1 (16.7)	2 (14.3)

LRTI; lower respiratory tract infection, AKI; Acute Kidney Injury, NSTEMI: non systemic myocardial infarction

Most participants (11/12) reported the intervention was comfortable or very comfortable, one felt it was uncomfortable. Three quarters (9/12) felt that the frequency of therapy and the length of sessions were about right, the remaining said that the sessions were too frequent and too long. When asked how easy or difficult the therapy was, over half (7/12) reported it was moderate or easy. The remaining five reported it was difficult. Almost all (11/12) reported therapy was given at the right stage of their recovery, one thought it was too early. (Table 6.8).

6.4.3 Treatment fidelity

Field notes were taken during the therapy sessions and themes were elicited and summarised using NVivo 12. Table 6.9. There were several technical challenges that arose such as poor signal from the electrodes and noise interference from a range of sources. On a few occasions, participants were unable to consistently control other physical movements of the head and neck that produced a signal and made the swallow difficult to distinguish.

Table 6-8 Participant responses to acceptability questionnaire

Question	Response n=12 (92.3%)		
How easy/difficult was the swallowing therapy you were doing …?	Easy	Reasonable	Difficult
	1 (8.3%)	6 (50.0%)	5 (41.7%)
How comfortable did you feel doing the swallowing therapy?	Very comfortable	Comfortable	Uncomfortable
	2 (16.7%)	9 (75.0%)	1 (8.3%)
Did you feel the frequency of the swallowing therapy was …?	Too little	About right	Too much
	0 (0.0%)	9 (75.0%)	3 (25.0%)
Were the swallowing therapy sessions …?	Too short	About right	Too long
	0 (0.0%)	9 (75.0%)	3 (25.0%)
Having the therapy at this stage of your recovery – was it …?	Too early	Right time	Too late
	1 (8.3%)	11 (91.7)	0 (0.0%)

Table 6-9 Themes emerging from Biofeedback therapy session field notes

Themes	Subthemes	Number of participants affected	Number of occurrences
Technical Challenges	No or poor sEMG signal	8	15
	Noise	8	16
	Associated physical movements	5	11
Barriers to success	Difficulty eliciting repetitive swallows	11	34
	Failed skill training	11	28
	Physical or mental health issues	10	47
Facilitatory strategies	Mouthcare or fluids	7	11
	Technical strategies	7	11
	Verbal feedback	6	11
	Imagery	4	7
	Relaxation and breathing	2	4

It is important to highlight that most participants especially early on in the intervention were unable to complete the effortful swallow aspect of the strength training due to difficulties eliciting a swallow every 30s. Therefore, they practiced achieving these repetitive swallows until they were able to employ the effortful swallow strategy. This did improve as the sessions

went on for most participants. Similarly, most participants were unable to complete the skill training blocks and were often replaced with further strength training as per the protocol. Those that did, more often towards the last few sessions of the intervention, were unable to complete the amplitude target, only achieving success with the timing target.

Most participants at some point during their sessions complained of some form of physical or mental health concern. Fatigue was the most common concern and was the main reason for sessions being shorter than the 45-minute target. Several strategies were employed to address the barriers to successful sessions. To improve the sEMG signal and reduce noise, all electrical items attached to or close to the participants were moved or disconnected from the mains. Participants with facial hair were shaved and chins were cleaned prior to placing electrodes. Surgical tape and bandages were used to secure electrodes on occasions. Participants also benefitted from regular mouthcare or sips of fluids, mental imagery, verbal feedback and relaxation or breathing exercises to help elicit swallows when this was a problem.

6.4.4 Secondary outcomes

6.4.4.1 Clinical and swallow function outcomes

Swallow function (FOIS) improved in the treatment group and maintained in the control group but the difference between groups was not significant, odds ratio (OR) 0.29 (95% CIs 0.1-1.2, p =0.09). Swallow severity (DSRS) reduced in both groups and whilst there was greater improvement in the treatment group this was not significant, mean difference (MD) -1.1 (95% CIs -3.3-1.1, p=0.3). PAS score for 5ml thin liquids improved in the Biofeedback group and worsened slightly in the control group but the mean difference at two weeks was not significant between groups (MD -0.3, 95% CIs 1.9-0.3, p=0.1). Swallowing QOL (DHI) improved

in both groups, with the control group showing greater improvement at two weeks, although the mean difference between groups was not significant (MD 0.2, 95% CIs -6.2-22.9, p=0.3). Tables 6.10 & 6.11.

None of the trends in improvement in the biofeedback group vs the control group reached significance when adjusted for baseline FOIS and NIHSS but when adjusted for baseline scores FOIS, PAS and DHI were approaching significance. At 90 days there were no differences in swallowing between groups. Stroke severity remained significantly greater in the biofeedback group at two weeks, but not at 90 days. Length of stay was longer in the biofeedback group than the control group 92.0 days vs 52.0 days and mood was lower in the treatment group (SDSS 3 vs 0) but these were not significant. There was no other observable or statistical difference between the groups in non-adjusted and adjusted analyses.

6.4.4.2 Swallow physiology

There were no significant differences between groups at baseline or two weeks for mean 5ml L0 or worst puree (WP) boluses. Tables 6.12, 6.13, 6.14.

Table 6-10 Unadjusted and adjusted secondary swallowing and clinical outcomes at two weeks and 90 days post intervention

Variable	Total n=27	Biofeedback n=12	Control n=15	Unadjusted		Adjusted	
				MD/OR (95% CIs)	P value	MD/OR (95% CIs)	P value
2 weeks							
Dysphagia severity (DSRS)	3.8 (2.8)	3.2 (3.2)	4.3 (2.3)	-1.1 (-3.3-1.1)	0.316	-0.16 (-3.29-1.51)	0.450
Dysphagia function (FOIS)	5 [2]	5 [3]	4 [2]	0.29 (0.1 – 1.2)	0.094	4.23 (0.86-20.85)	0.077
DTNAx Scale* /7 (n=23)	2 [3]	1.5 [3]	2 [3]	2.4 (0.5 – 10.4)	0.250	0.77 (0.14-4.17)	0.757
PAS 5ml thin fluids (mean) (n=26)	2.6 (1.4)	2.1 (1.4)	3.0 (1.3)	-0.3 (-1.9-0.3)	0.138	-0.19 (-1.72-0.70)	0.387
PAS 50mls thin fluids (n=26)	3.8 (1.9)	3.2 (1.4)	4.4 (2.1)	-0.30 (-2.67-0.40)	0.141	-0.18 (-2.36-1.01)	0.411
PAS 5ml puree (worse) (n=26)	1.8 (1.6)	1.6 (1.2)	2.0 (1.9)	-0.13 (-1.75-0.92)	0.526	-0.00 (-1.46-1.41)	0.987
Feeding route							
Oral diet – normal	7 (25.9)	5 (41.7)	2 (13.3)	3.48 (0.76-15.96)	0.109	3.75 (0.68-20.64)	0.129
Oral diet - modified	13 (48.1)	5 (41.7)	8 (53.3)				
NG feeding	7 (25.9)	2 (16.7)	5 (33.3)				
PEG feeding	0 (0)	0 (0)	0 (0)				
Other	0 (0)	0 (0)	0 (0)				
Swallowing QOL (DHI)	22.7 (18.1)	27.2 (21.9)	18.9 (13.7)	0.23 (-6.2 – 22.9)	0.250	0.30 (-5.74-27.01)	0.192
NIHSS (n=25)	8.4 (4.5)	10.3 (4.3)	6.7 (4.1)	3.6 (0.1 – 7.0)	**0.046**	-0.05 (-2.46-1.62)	0.674
mRS	4 [1]	4.5 [1]	4 [0]	0.2 (0.0 – 1.2)	0.086	1.99 (0.28-14.21)	0.493
Barthel Index	25.6 (23.2)	16.3 (8.3)	33.6 (28.8)	-17.3 (-35.1 – 0.5)	0.056	-0.13 (-22.06-10.46)	0.468
Mood (SDSS)	1 [2.3]	1 [0.5]	0.5 [3]	0.71 (0.2 – 2.9)	0.638	1.28 (0.26-5.62)	0.802
90 days							
Dysphagia severity (DSRS)	2.0 (3.9)	2.1 (4.2)	2 (3.8)	0.1 (-3.1-3.3)	0.957	-0.05 (-4.04-3.27)	0.829
Dysphagia function (FOIS)	7 [2]	7 [1]	7 [2]	0.4 (0.3 – 7.2)	0.711	1.47 (0.24-8.92)	0.673

Variable	Total n=27	Biofeedback n=12	Control n=15	Unadjusted		Adjusted	
				MD/OR (95% CIs)	P value	MD/OR (95% CIs)	P value
Feeding route (n=25)							
Oral diet – normal	19 (76.0)	9 (81.9)	10 (71.4)	1.41 (0.27-7.44)	0.688	1.54 (0.26-9.36)	0.637
Oral diet - modified	3 (12.0)	1 (9.1)	2 (14.3)				
NG feeding	0 (0)	0 (0)	0 (0)				
PEG feeding	3 (12.0)	1 (9.1)	2 (14.3)				
Swallowing QOL (DHI)	24.2 (25.8)	24.1 (27.4)	24.3 (25.4)	-0.3 (-21.2-20.7)	0.981	0.03 (-22.75-25.87)	0.895
NIHSS (n=23)	10.2 (10.7)	13 (10.7)	7.9 (10.6)	5.1 (-3.8-14.0)	0.250	0.08 (-8.30-11.76)	0.723
mRS	4 [1]	4 [1]	4 [2]	0.5 (0.1-2.2)	0.402	0.76 (0.15-3.81)	0.735
Barthel Index	38.4 (31.5)	30.3 (26.1)	44.9 (34.8)	-14.6 (-39.5 – 10.3)	0.239	-0.11 (-34.81-21.06)	0.616
Mood (SDSS)	2 [3]	3 [2]	0 [3]	0.4 (0.1-1.8)	0.244	2.25 (0.45-11.20)	0.324
Length of stay	69.8 (41.8)	92.0 (42.6)	52.0 (32.4)	40.0 (10.3-69.7)	**0.010**	0.20 (-8.67-42.18)	0.186
Pneumonia	8 (29.6)	4 (33.3)	4 (26.7)	0.73 (0.14-3.82)	0.707	1.03 (0.15-6.82)	0.979
Pneumonia & LRTIs	10 (37.0)	5 (41.7)	5 (33.3)	0.70 (0.15-3.37)	0.656	0.80 (0.12-5.40)	0.818
Death	2 (7.4)	1 (8.3)	1 (7.1)	0.79 (0.04-14.03)	0.870	1.20 (0.04-32.19)	0.916
Discharge destination							
1.Home	17 (63.0)	7 (58.3)	10 (66.7)	0.55 (0.12-2.57)	0.450	0.82 (0.14-4.92)	0.825
2.Residential home	2 (7.4)	0 (0)	2 (13.3)				
3.Nursing home	5 (18.5)	3 (25.0)	2 (13.3)				
4.Remains inpatient	3 (11.1)	2 (16.7)	1 (6.7)				

Data are number (%), median [interquartile range] or mean (standard deviation), and odds ratio or mean difference (95% confidence intervals). Comparison by binary logistic regression (BLR), ordinal logistic regression (OLR) or multiple linear regression (MLR).

Table 6-11 Mean change and group comparisons for swallowing outcome measures

Measure	Biofeedback				Control				Comparisons	
	Baseline	2 weeks	Mean change	Within group t-test or Wilcoxon	Baseline	2 weeks	Mean change	Within group t-test or Wilcoxon	Between group t-test or MWU - unadjusted	Between group ANCOVA/OLR adjusted for baseline score
DSRS	6.3	3.2	-3.2	**0.000**	6.3	4.3	-2.1	**0.003**	0.316	0.203
FOIS	3	5	+1.9	**0.005**	4	4	+1	**0.008**	0.103	0.050
DTN	3.5	1.5	-1.8	**0.005**	3	2	-1.5	**0.019**	0.259	0.250
DHI	29.6	27.2	0	0.552	25.9	18.9	-7.6	0.066	0.250	0.071
PAS 5ml	3.2	2.1	-1.1	0.072	2.6	3	+0.4	0.412	0.138	0.071
PAS 50ml	4.0	3.2	-0.7	0.363	4.7	4.4	+0.2	0.742	0.114	0.086
PAS puree	1.4	1.6	+0.2	0.689	1.6	2.0	+0.3	0.572	0.526	0.538

Table 6-12 Adjusted and unadjusted baseline and post intervention 5ml Level 0 fluid bolus videofluoroscopy timing, displacement and efficiency measures

	Baseline			Post intervention			Unadjusted		Adjusted for NIHSS & FOIS	
Variable Mean (SD)	Total n=26	Biofeedback n=12	Control n=14	Total n=26	Biofeedback n=12	Control n=14	MD/OR (95% CIs)	P value	MD/OR (95% CIs)	P value
Global Oral Transit Time (GOTT) (s)	1.31 (2.56)	0.92 (1.37)	1.64 (3.28)	0.96 (1.27)	0.85 (0.72)	1.05 (1.63)	-0.08 (-1.26-0.85)	0.690	-0.12 (-1.48-0.90)	0.617
Stage Transition Duration (STD) (s)	0.74 (0.82)	0.73 (0.57)	0.75 (1.01)	0.54 (0.77)	0.51 (0.56)	0.56 (0.94)	-0.03 (-0.69-0.60)	0.887	-0.08 (-0.85-0.62)	0.749
Pharyngeal Reaction Time (PRT) (s)	0.89 (0.20)	0.92 (0.17)	0.87 (0.22)	0.99 (0.43)	0.93 (0.19)	1.05 (0.56)	-0.15 (-0.48-0.23)	0.470	-0.04 (-0.39-0.32)	0.836
Pharyngeal Transit time (PTT) (s)	1.61 (0.84)	1.57 (0.53)	1.63 (1.04)	1.53 (0.85)	1.44 (0.59)	1.60 (1.05)	-0.09 (-0.86-0.55)	0.658	-0.08 (-0.92-0.65)	0.725
Laryngeal Vestibular Closure (LVC) (s)	0.35 (0.10)	0.35 (0.09)	0.35 (0.11)	0.36 (0.14)	0.34 (0.17)	0.38 (0.11)	-0.16 (-0.16-0.07)	0.438	-0.01 (-0.13-0.13)	0.960
Laryngeal Closure Duration (LCD) (s)	0.51 (0.14)	0.51 (0.16)	0.52 (0.12)	0.48 (0.17)	0.47 (0.13)	0.49 (0.20)	-0.06 (-0.16-0.12)	0.785	0.02 (-0.16-0.15)	0.944
Upper Oesophageal Sphincter closure duration (UES) (s)	0.67 (0.20)	0.71 (0.21)	0.64 (0.19)	0.76 (0.43)	0.70 (0.19)	0.81 (0.56)	-0.13 (-0.46-0.24)	0.521	-0.08 (-0.43-0.30)	0.703
Maximum Hyoid Elevation duration (MHE) (s)	0.27 (0.12)	0.29 (0.12)	0.25 (0.13)	0.29 (0.10)	0.29 (0.10)	0.30 (0.10)	-0.9 (-0.10-0.07)	0.679	-0.11 (-0.19-0.08)	0.647
Anterior Hyoid displacement (AHD) (cm)	0.72 (0.30)	0.76 (0.26)	0.68 (0.34)	0.79 (0.30)	0.86 (0.30)	0.72 (0.29)	0.25 (-0.10-0.38)	0.229	0.18 (-0.17-0.38)	0.437
Superior Hyoid Displacement (SHD) (cm)	1.22 (0.57)	1.24 (0.57)	1.21 (0.59)	1.00 (0.61)	1.20 (0.74)	0.84 (0.44)	0.30 (-0.13-0.84)	0.139	0.38 (-0.09-1.01)	0.098
MBSImP #16 Pharyngeal Residue (/4)	2 (1)	1.5 (1)	2 (1)	2(1)	1 (1)	2 (1)	2.78 (0.58-13.41)	0.202	2.64 (0.48-14.61)	0.265
MBSImP #5 Initiation of Pharyngeal Swallow (/4)	3 (1.25)	2(1)	3 (2)	2 (2)	2 (2.5)	2(2)	1.44 (0.36-5.21)	0.605	1.12 (0.23-5.41)	0.890

Table 6-13 Adjusted and unadjusted baseline and post intervention 5ml Puree Videofluoroscopy timing, displacement and efficiency measures

Variable Mean (SD)	Baseline			Post intervention			Unadjusted		Adjusted for NIHSS & FOIS	
	Total n= 26	Biofeedback n=12	Control n=14	Total n= 26	Biofeedback n=12	Control n=14	MD/OD (95% CIs)	P value	MD/OD (95% CIs)	P value
Global Oral Transit Time (GOTT) (s)	2.49 (4.16)	0.63 (0.52)	3.88 (5.18)	1.67 (1.91)	1.04 (0.87)	1.99 (2.24)	-0.24 (-3.23-1.33)	0.385	-0.38 (-4.73-1.79)	0.342
Stage Transition Duration (STD) (s)	0.93 (1.10)	1.23 (0.70)	1.19 (0.68)	0.96 (1.05)	1.34 (1.19)	0.58 (0.75)	0.37 (-0.13-1.65)	0.088	0.40 (-0.21-1.84)	0.113
Pharyngeal Reaction Time (PRT) (s)	1.02 (0.44)	0.90 (0.13)	1.12 (0.57)	1.37 (1.23)	1.40 (1.22)	1.36 (1.28)	0.02 (-1.06-1.14)	0.942	0.09 (-0.98-1.41)	0.709
Pharyngeal Transit time (PTT) (s)	1.87 (0.95)	2.04 (0.85)	1.75 (1.03)	1.99 (1.11)	2.42 (1.19)	1.57 (0.87)	0.39 (-0.14-1.83)	0.088	0.45 (-0.18-2.13)	0.093
Laryngeal Vestibular Closure (LVC) (s)	0.35 (0.33)	0.31 (0.21)	0.38 (0.41)	0.41 (0.16)	0.39 (0.14)	0.42 (0.17)	-0.10 (-0.16-0.10)	0.640	-0.03 (-0.16-0.14)	0.906
Laryngeal Closure Duration (LCD) (s)	0.55 (0.18)	0.56 (0.18)	0.54 (0.18)	0.47 (0.19)	0.49 (0.21)	0.45 (0.18)	0.09 (-0.12-0.20)	0.652	0.18 (-0.11-0.25)	0.425
Upper Oesophageal Sphincter closure duration (UES) (s)	0.71 (0.44)	0.67 (0.13)	0.74 (0.60)	0.86 (0.95)	0.71 (0.24)	0.99 (1.27)	-0.15 (-1.09-0.53)	0.479	-0.11 (-1.00-0.60)	0.611
Maximum Hyoid Elevation duration (MHE) (s)	0.26 (0.11)	0.29 (0.09)	0.25 (0.12)	0.28 (0.12)	0.27 (0.14)	0.28 (0.11)	-0.04 (-0.11-0.09)	0.839	-0.05 (-0.12-0.10)	0.819
Anterior Hyoid displacement (AHD) (cm)	0.89 (0.37)	0.93 (0.27)	0.87 (0.45)	0.77 (0.29)	0.68 (0.21)	0.86 (0.32)	-0.32 (-0.41-0.05)	0.117	-0.24 (-0.39-0.12)	0.272
Superior Hyoid Displacement (SHD) (cm)	1.21 (0.68)	1.23 (0.70)	1.19 (0.68)	1.30 (0.55)	1.26 (0.54)	1.34 (0.58)	-0.07 (-0.54-0.38)	0.719	-0.03 (-0.54-0.47)	0.895
MBSImP #16 Pharyngeal Residue (/4)	2 (1)	1.5 (1)	2 (1)	2 (1)	1.5 (1)	2 (1)	1.88 (0.39-8.98)	0.431	1.54 (0.26-9.00)	0.631
MBSImP #5 Initiation of Pharyngeal Swallow (/4)	1 (1)	1 (1.5)	1 (1)	1 (0.75)	1 (1)	1 (1)	0.29 (0.06-1.50)	0.139	0.47 (0.08-2.72)	0.402

Anterior hyoid displacement on 5ml L0 significantly increased from 0.75cm at baseline to 0.79cm at two weeks (t(24)=-2.3, p=0.03) across groups and although there was a larger increase in the biofeedback group there was no significant difference between groups at two weeks (MD 0.18, 95% CIs -0.17-0.38, p=0.4).

Table 6-14 Average number of swallows per bolus for the 5ml Level 0 and 5ml worst puree

	All (n=26)		Biofeedback (n=12)		Control (n=14)		ANOVA Repeated measures
Mean number swallows	Baseline	2 weeks	Baseline	2 weeks	Baseline	2 weeks	
Mean 5ml L0	1.42 (0.49)	1.48 (0.83)	1.50 (0.54)	1.56 (1.15)	1.35 (0.46)	1.42 (0.46)	>0.05 for time and group
Worst 5ml puree	1.19 (0.40)	1.50 (0.71)	1.25 (0.45)	1.50 (0.90)	1.14 (0.36)	1.50 (0.52)	0.011 *time no group effect

Laryngeal closure duration (LCD) significantly decreased in the WP bolus from 0.55s baseline to 0.47s at two weeks (t(25)=2.3, p= 0.03), and mean number of swallows to clear the WP bolus significantly increased from 1.2 to 1.5 (t(25)=-2.9, p=0.008) but there was no difference between groups. There were no differences between groups in 50ml L0 efficiency measures at two weeks. Table 6.15.

Table 6-15 Post intervention Videofluoroscopy 50mls thin fluids efficiency measures

				Unadjusted		Adjusted		ANCOVA/ OLR adjusted for baseline p value
Variable	Total	Biofeedback	Control	MD/OD (95% CIs)	P value	MD/OD (95% CIs)	P value	
2 weeks								
Number of swallows (n=23)	7.5 (4.3)	8.0 (4.2)	7.1 (4.5)	0.11 (-2.86-4.69)	0.619	0.32 (-1.12-6.50)	0.155	0.787
Time taken (n=25)	34.8 (19.7)	35.7 (16.3)	34.0 (23.0)	0.05 (-14.9-18.4)	0.829	0.17 (-9.38-22.50)	0.402	0.777
MBSImP #4 Bolus transport	0 (0)	0 (0.5)	0 (0)	0.57 (0.08-1.15)	0.580	0.66 (0.07-6.17)	0.715	0.926
MBSImP #16 Pharyngeal Residue	2 (1)	2 (1)	2 (1)	1.13 (0.21-6.05)	0.891	1.35 (0.21-8.77)	0.755	0.904

6.4.5 Reliability videofluoroscopy analysis

Mean VFS timing, displacement and clearance measures could not be calculated for every participant due to missing data, which is captured within the results tables above. The mean of the worst, best and mode boluses was reported but data were not always available for each of the boluses. Table 6.16 explores this in more detail and shows the number of missing scores for each component which also includes the WP bolus. GOTT, PTT, PRT and UESD were most vulnerable to missing data. Reasons for missing data were; shoulder obscuring, out of frame, contrast poor, collimation issue, not screened, C2-C4 unclear, hyoid rest prior to swallow unclear, moving image, contrast obstructing, residue, wrong orientation.

Table 6-16 Missing VFS data across the worst, best, mode and worst puree boluses

Score	Number of missing data (/104)
Global Oral Transit Time (GOTT)	48
Stage Transition Duration (STD)	13
Pharyngeal Reaction Time (PRT)	21
Pharyngeal Transit time (PTT)	27
Laryngeal Vestibular Closure (LVC)	5
Laryngeal Closure Duration (LCD)	3
Upper Oesophageal Sphincter closure duration (UESD)	18
Maximum Hyoid Elevation duration (MHE)	7
Anterior Hyoid displacement (AHD)	12
Superior Hyoid Displacement (SHD)	12
MBSImP #16 Pharyngeal Residue	3
MBSImP #6 Initiation of Pharyngeal Swallow (IPS)	9

Inter rater reliability was moderate for PAS, strong to perfect for the timing and duration measures, minimal to moderate for efficiency measures and good to perfect for displacement measures. Table 6.17.

Intra-rater reliability was moderate for PAS, strong to perfect for the timing and duration measures, weak to strong for efficiency measures and moderate to good for displacement measures. Table 6.18.

Table 6-17 Inter rater reliability of Videofluoroscopy measures

Measure	ICC/weighted Kappa	Lower CIs	Upper CIs	Interpretation
TF1 (n=17)	1.0	1.0	1.0	Perfect
TF2 (n= 24)	0.993	0.985	0.997	Excellent
TF3 (n= 24)	1.0	1.0	1.0	Perfect
TF4 (n= 24)	1.0	1.0	1.0	Perfect
TF5 (n= 21)	1.0	1.0	1.0	Perfect
TF6 (n= 24)	1.0	1.0	1.0	Perfect
TF7 (n= 24)	1.0	1.0	1.0	Perfect
TF8 (n= 24)	1.0	1.0	1.0	Perfect
TF9 (n= 24)	1.0	1.0	1.0	Perfect
TF10 (n= 18)	1.0	1.0	1.0	Perfect
MBSImP#4	0.333	0.018	0.649	Minimal
MBSImP #5	0.613	0.314	0.912	Moderate
MBSImP #6	0.822	0.696	0.949	Strong
MBSImP #16	0.538	0.290	0.787	Weak
PAS (n= 24)	0.701	0.424	0.859	Moderate
HSrest (n=18)	0.942	0.852	0.978	Good
HArest (n=18)	0.948	0.865	0.980	Good
HSmax (n=20)	0.966	0.917	0.987	Perfect
HAmax (n=21)	0.880	0.665	0.954	Good

TF = timing frame, HS rest – resting superior hyoid from C2-C4 perpendicular plane, HA rest = resting anterior hyoid from C2-C4 plane. HSmax = max superior hyoid from C2-C4 perpendicular plane HAmax = max anterior hyoid from C2-C4 plane.

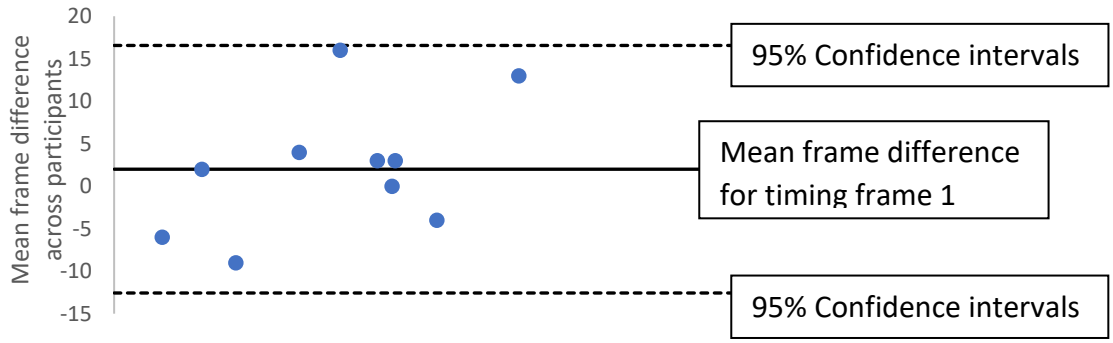
A further analysis was carried out to verify whether the ICCs for the timing measures TF1-TF10 were accurate. Exploring the difference in ratings, between raters the majority are perfect or very close i.e. within five frames. However, there are some timing frames i.e., TF1 where there are examples of scores with 13, 6, 9, 16 frames difference. Yet the ICCs are 1.0 for most. A Bland Altman plot with TF1 was carried out showing that all the difference scores fell within the 95% CIs - suggesting good reliability[324]. Figure 6.4

Table 6-18 Intra-rater reliability of videofluoroscopy measures

Measure	ICC/weighted Kappa	Lower CIs	Upper CIs	Interpretation
TF1 (n=11)	1.0	1.0	1.0	Perfect
TF2 (n= 22)	1.0	1.0	1.0	Perfect
TF3 (n= 23)	1.0	1.0	1.0	Perfect
TF4 (n= 23)	1.0	1.0	1.0	Perfect
TF5 (n= 23)	1.0	1.0	1.0	Perfect
TF6 (n= 23)	1.0	1.0	1.0	Perfect
TF7 (n= 24)	1.0	1.0	1.0	Perfect
TF8 (n= 24)	1.0	1.0	1.0	Perfect
TF9 (n= 23)	1.0	1.0	1.0	Perfect
TF10 (n= 16)	1.0	1.0	1.0	Perfect
MBSImP#4 (n=21)	0.825	0.628	1.022	Strong
MBSImP #5 (n=24)	0.429	0.051	0.807	Weak
MBSImP #6 (n=23)	0.930	0.836	1.023	Strong
MBSImP #16 (n=24)	0.776	0.579	0.973	Moderate
PAS (n= 39)	0.703	0.503	0.832	Moderate
HSrest (n=20)	0.671	0.346	0.854	Moderate
HArest (n=20)	0.684	0.350	0.862	Moderate
HSmax (n=20)	0.838	0.635	0.932	Good
HAmax (n=20)	0.547	0.141	0.794	Moderate

TF = timing frame, HS rest – resting superior hyoid from C2-C4 perpendicular plane, HA rest = resting anterior hyoid from C2-C4 plane. HSmax = max superior hyoid from C2-C4 perpendicular plane HAmax = max anterior hyoid from C2-C4 plane.

Figure 6-4 Bland Altman chart exploring intra-rater reliability for timing frame 1



6.4.6 Usual care

Usual care consisted of a mean of 2.6 sessions (SD 1.3) that lasted an average of 24.6 minutes (SD 7.0). 73.2% of the sessions involved assessment alone, 16.9% focussed on patient and/or

family education with or without further assessment and 9.9% involved dysphagia rehabilitation.

6.5 Discussion

This study investigated the feasibility and acceptability of swallow skill and strength training with sEMG biofeedback in an acute stroke setting.

Once participants were recruited, the criteria for determining feasibility, a compliance rate of 80% was achieved. The study recruited 90% of the planned sample size of 30. The main reason the target of 100% was not met was due to limited researcher capacity. The author who also worked clinically during the recruitment period, was the sole individual screening, approaching and consenting patients and also delivering the intervention. This meant that only two participants could be enrolled at any one time. A large number of participants (n=97) were excluded due to exceeding the cut off of four weeks post stroke, many of these were otherwise eligible, but had been on a waiting list to be approached by the researcher when capacity arose. Mitigating for issues with screening, approaching and consenting would be straightforward in a larger trial by using Clinical Research Networks. However, further work developing and testing approaches to delivering this intervention by clinical rather than research teams within acute stroke settings is needed prior to a larger trial. The intervention was safe and it was acceptable to participants in terms of comfort, session length and frequency and timing of the intervention. Some participants found the intervention challenging but this is important in maximising neuroplasticity in stroke rehabilitation [46].

Observations on treatment fidelity indicated that increasing the strength or controlling the timing of the swallow was not possible for all patients initially but developed over time. Repetitive swallowing practice is task-specific and the repetitive nature provides the challenge that is thought to be necessary to enhance neuroplasticity in strength and skill training[45]. The treatment protocol for future larger studies will need to incorporate this first step of achieving repetitive swallows prior to progressing to the strength and skill tasks. Further, there were technical and practical aspects of the intervention that were identified, such as methods to reduce electrical noise, ways to secure electrodes in place and need for verbal feedback and encouragement as well as the visual biofeedback that would need to be incorporated into the protocol of future studies.

Whilst compliance was generally excellent at 80%, one participant was unable to complete any sessions partially or completely due low mood. Fatigue was a factor that impacted on participants completing all sessions and reduced session length. This is likely due to the study being conducted with acute stroke patients and the average session length should be taken into account in future dose optimising studies.

Clinical signals in treatment effect were found in trends towards greater improvement in swallowing safety, function and severity measures in the biofeedback group. These were not statistically significant but the trial was powered to assess feasibility and acceptability and not clinical efficacy. The biofeedback group showed >1 point more improvement than the control group in the DSRS and the FOIS which has been demonstrated as a minimal clinically important difference with both of the scales [225]. Significant improvements in swallow function and severity have been seen previously in smaller observational studies with chronic patients [286].

The PAS also non-significantly improved in the treatment group. The mean PAS of the four L0 boluses per participant were calculated and treated as a continuous variable in this study. A systematic review however, showed that studies vary in their methodology for analysing PAS. Although many studies treat the scale as continuous and use parametric statistics, most studies treat it as ordinal and use non-parametric statistics [325]. The scale has been criticised for not being a fully ordinal scale, and as a result a number of studies have produced ordinal categories, the most recent proposes four categories; A = no material remains in the laryngeal vestibule or trachea post swallow (PAS scores 1, 2, or 4), B = uncleared penetration/aspiration where a part of the bolus remains in the laryngeal vestibule above the vocal cords (PAS scores 3 or 6), C = aspiration with a sensory response (PAS = 7), D = aspiration with no sensory response (PAS = 8) [326]. The choice of which bolus to score or whether to average over several boluses also varies between studies. In the latter review paper, the suggestion is to use the worst PAS score from a set of boluses, converted into a category and analyse with ordinal logistic regression. However, this may not give a true representation of the variability within participants, for example a patient may score PAS = 1 on three out of four boluses but score 7 on one of the four. Non-parametric tests also require greater numbers to achieve the power of a parametric test. There is no current consensus on how to analyse, but it is important to clearly report the analysis used so they can be compared.

The DHI showed a greater non-significant improvement in QOL in the control group. DHI score has been correlated to greater NIHSS and time post stroke [327] therefore this may account for observed differences. The data collectors questioned participant's insight into their dysphagia in order to answer the questions in the DHI accurately based on their current situation. Thus, it remains unclear how post stroke cognitive impairments such as insight and

memory impact on patient's ability to answer the questions in the DHI. Previous studies have found the DHI impractical to administer, which was also noted in this study [327].

The effortful swallow has been shown to increase pharyngeal pressure [328], maximal hyoid excursion and duration [329], duration of laryngeal vestibular closure (LVC) and duration of upper oesophageal sphincter (UES) opening in healthy adults [130, 330, 331] although its effects on disordered swallowing are still unclear [328]. Changes in swallow physiology using VFS have not previous been investigated following swallow skill training using timing and amplitude alone. In this study VFS was used to look for changes in swallow physiology but there were no significant differences between groups in timing, duration or efficiency measures described above. A greater increase in anterior hyoid displacement with 5ml L0 was found in the biofeedback group as has been found in previous studies using the effortful swallow [332], but this was not significant and reduced displacement was observed in the WP bolus.

The main objective of this study was to demonstrate feasibility and was not powered to test effectiveness therefore little can be concluded from these secondary outcomes. As the FOIS, DSRS and PAS were the strongest outcome measures, they should be considered for the primary outcome in future studies. Using the DSRS data to inform the sample size of an efficacy trial (assuming DSRS difference between groups 1.1 points, SD 3.2, power 90%, alpha 5%, compliance 80%, dropout rate 5%) a sample of 450-500 participants would be needed to detect a treatment effect. Knowing whether the intervention can be delivered across multiple sites with effective staff training or is beneficial using different regimens is also unclear and would need to be tested prior to a phase III study.

The intervention, which on average over two weeks involved 8.7 x 36.2 minute sessions, was more intensive compared to 2.6 x 24.6 minutes of usual care which primarily focussed on assessment. It is also unclear whether intensive strength and skill training without biofeedback is, on its own effective in improving dysphagia. Thus, including a usual care group or sham biofeedback group with the same intensity of intervention as the treatment group would be indicated in a larger study to understand whether biofeedback does enhance effectiveness. Timing of administration of the intervention also needs careful consideration since post stroke dysphagia recovers at a greater rate in the first days to weeks post stroke compared to months later[333]; indeed, all participants in this study made an excellent swallow recovery by day 90. The effect size of intervention therefore may differ according to the stage of recovery and plasticity of the brain. Similarly, little is known about effective dose of this intervention including total number, length and frequency of sessions, which again may vary according to the time of administration.

6.5.1 Limitations

The present study was strengthened by multiple efforts to avoid bias in this prospective, randomised controlled trial with consecutive recruitment and allocation of concealment into the treatment or control group; researchers analysing the VFS and collecting 90-day data were blinded to treatment allocation; and the protocol and statistical analysis plan were published in advance. Data were collected on treatment fidelity which can help to strengthen the treatment protocol for future studies. However, trial limitations include the small sample size and broad time window of inclusion leading to an imbalance in baseline stroke severity between groups (and subsequently in length of stay and DHI), despite the use of minimisation at randomisation. Importantly, baseline swallow severity was equal in both groups allowing

for fair comparisons in swallow outcomes. Understandably, dysphagia severity does correlate with stroke severity[225], [225]and notwithstanding prespecified statistical adjustments in baseline FOIS and NIHSS, the imbalance could still confound the results in favour of the control (less severe) group and thereby dilute any potential treatment effect. Finally, post intervention data at two weeks was collected by the same researcher unblinded to delivery of the intervention, therefore introducing a performance bias. This was due to resource limitations but would need to be factored into a larger study.

6.5.2 Conclusions

Strength and skill training with sEMG biofeedback is safe and acceptable to acute stroke patients. Delivering the intervention was feasible in those recruited and treatment fidelity data demonstrated adaptations that were incorporated to achieve this. Further research into feasibility of delivering the intervention by clinical teams in acute stroke, optimal dose and effectiveness of treatment is indicated. Greater improvements in swallow severity, function and PAS were observed in the treatment group post intervention, these were not significant, but either of these could be considered as a primary outcome in future studies. Further consideration needs to be made as to a suitable control group to determine whether outcomes are related to intensity of therapy or augmentative effects of biofeedback.

Chapter 7: Summary and Conclusions

The opening chapter gives an introduction to post stroke dysphagia, with an overview of the latest research on its assessment and rehabilitation.

7.1 Summary of research into comprehensive screening tests

The second chapter of this thesis systematically reviewed the literature around comprehensive screening tests for dysphagia for use in acute stroke that can be carried out by trained non-specialists. Five tests were identified, three of which had been validated for the identification of aspiration and in some cases dysphagia. Questions over the content validity of the tests was discussed, highlighting safety concerns that patients with dysphagia are recommended modified diet and fluids that had not been directly tested. Diagnostic accuracy of these tests was also variable, in the case of the GUSS demonstrating excellent sensitivity for identification of aspiration but lower specificity. Resulting in many patients unnecessarily remaining NBM until further assessment. Overall, diagnostic accuracy for identifying dysphagia was better with the VVST although as with the GUSS, the quality of the studies was also questionable and may invalidate the results. Training requirements were also limited in many of the tests, with no training required to administer the BESST. The DTNAx takes longer than the other assessments to carry out and little was known about its concurrent validity, but it demonstrated superior content validity and its training requirements are in line with the Interprofessional Dysphagia Framework.

In the third chapter, the DTNAx was tested for diagnostic accuracy in identification of aspiration compared to VFS and dysphagia compared to SLTAx and VFS. It demonstrated good accuracy for recognising aspiration, but numbers of aspirators were relatively small so

confidence intervals were high. Reassuringly there were few false negatives but several false positives. The majority of these cases were found to demonstrate airway penetration on VFS therefore this is interpreted as a positive outcome as greater volumes of material deeper in the airway pose a higher risk for negative respiratory consequences. It also brought into question whether a PAS score of >2 should be considered as the cut off on VFS if used as a 'gold standard' reference assessment in diagnostic accuracy studies. The accuracy of the DTNAx in identifying dysphagia compared to SLTAx was excellent and recommendation accuracy was moderate to strong. Given that the study methodology aimed to reduce bias in order to deliver a high-quality piece of work, this is a very positive outcome. The prespecified definition for dysphagia on VFS based on MBSImP cut offs was inaccurate as all participants had dysphagia according to the definition. However, there is no universally agreed robust definition or accompanying assessment tool. Furthermore, the prespecified criteria to what constitutes a safe and efficient swallow for different diet and fluid textures was also interpreted to be conservative thus resulting in poor results in accuracy between DTNAx or SLTAx and VFS.

The fourth chapter explored the views of DTNs who work clinically in acute stroke. Overall, the role and the DTNAx pathway were viewed positively for both the nurses' job satisfaction but also for the patients. There were challenges on busy shifts to stick to the assessment and pathway as intended and some nurses questioned the use of the tool with very mild stroke patients. The training that is involved was recognised by the nurses as essential to the role. They reported needing to deviate from the strict proforma for various reasons such as availability of suitable food for trials, patient preferences or allergies and patient compliance.

7.2 Future directions in Comprehensive Screening Tests and the DTNAx

DTNs highlighted the challenges of carrying out the DTNAx when they had lots of admissions at one time, they questioned whether patients with very mild strokes such as only visual symptoms needed to have a full DTNAx. Other comprehensive screening tests, the VVST and the GUSS follow on from a preliminary non-water screening component to identify those who may be at risk of aspiration or dysphagia, those who do not qualify as at risk are not assessed and commence normal diet and fluids. The whole pathway (preliminary screen and test) has not been validated with consecutively admitted acute stroke patients for either of these tests. Therefore, it is unclear whether they accurately identify patients with dysphagia and or aspiration. Concerns regarding the content of these tests and quality of the validation studies have also been discussed.

It is possible that using a combined water swallow test and a comprehensive screening test could be a better solution. Water swallow tests have been shown to have high sensitivity in identifying those with dysphagia, but lower specificity and concerns over commencing patients on normal diets when solid textures have not been assessed. The water swallow test and the DTNAx could easily be combined and due to the cross over in content, the maximum time to complete would be the length of the DTNAx. The preliminary checks, oromotor screen and first part of the oral trials with water would remain the same. If no problems are identified on any of those sections – the patients are tested on normal diet (trialling consecutively more modified diets as per the assessment if concerns arise). If problems are identified on the preliminary checks, oromotor screen or water trials, the full DTNAx is completed. This would make the assessment process more efficient for busy nurses in acute stroke and address the challenges that they highlighted in the qualitative study.

A combined assessment rather than the DTNAx alone may be a more cost-effective pathway without impacting negatively on clinical outcomes. Further research could explore this in addition to investigating the outcomes of DTN assessed patients in the days and weeks post assessment. Additionally, the cost effectiveness of using comprehensive screening tests rather than water swallow tests has not been conducted but would be very important to know. These comprehensive assessments bring benefits of less patients being NBM and subsequently tube fed, possibly less time spent by SLTs when they initially see patients who have failed the assessment as many patients are already on oral intake. However, the training requirements for nurses, SLT time delivering training and nurse time spent conducting the longer comprehensive assessments may outweigh these benefits.

This thesis has shown that the level of training that nurses receive to carry out the DTNAx in acute stroke is essential, nurses valued updates, but little is known about how well they maintain their knowledge, how often updates are needed and in what format. Therefore, this could be explored further.

The DTNAx has a potential to be used as a standardised outcome measure of dysphagia in clinical trials by research nurses after undergoing training. Further analysis of data from Chapter 6 where the DTNAx was used as an outcome measure in a clinical trial could be used to further validate the tool. Sensitivity to change from pre to post intervention can be examined. Concurrent and predictive criterion validity with other dysphagia measures such as the DSRS, PAS and FOIS, and with clinical measures such as NIHSS, and mRS and BI can be analysed.

7.3 Summary of biofeedback as an adjunct to dysphagia therapy research

Chapter 5 systematically reviewed the literature into any kind of biofeedback as an adjunct to any kind of swallowing therapy with participants with any aetiology of dysphagia. In 23 studies, sEMG was the most common biofeedback tool used in the published studies paired with a range of task specific strength and skill exercises at different doses, across a range of patients. No non-controlled or n=1 studies were eligible for inclusion. Meta-analysis of only five eligible controlled studies with high heterogeneity in the intervention methods and in outcome measures demonstrated no favourable effects on swallow function or clinical outcomes. With regards to swallow physiology, significantly greater improvement in anterior hyoid displacement was seen in the biofeedback group compared to the control group. However due to the quality of the studies included, the results must be taken with caution. The need to target and measure intervention around specific impairments was discussed.

Chapter six described a randomised controlled feasibility study of strength and skill swallowing training with surface electromyographic biofeedback in acute stroke. The content of intervention was based on results from the systematic review and the literature. It involved strength and skill training with sEMG feedback using the BiSSkiT software at a dose of 10 x 45 minute sessions over two weeks. Twenty-seven participants were recruited, 12 completed the intervention in addition to usual care and 15 received usual care only. The intervention was feasible and acceptable to the participants recruited. Secondary outcomes showed greater increases in the biofeedback group in swallowing severity, function and PAS but these were not significant. Despite minimising for stroke severity, NIHSS in the treatment group was higher than the control group. No significant differences between groups were found on swallow physiology measures or clinical outcomes when adjusted for baseline stroke severity

and swallow function. Treatment fidelity showed that there were some challenges to delivering the intervention exactly as prescribed. Many participants were not able to start the intervention at the level pre-specified, so a step down to an additional level targeting practicing repetitive swallows was needed at the beginning of the intervention. This extra level would still fall under the domain of swallow strength and skill training and most patients were able to progress onto the predefined strength and skill exercises.

7.4 Future directions with biofeedback as an adjunct to dysphagia therapy

A poor overall quality of study design discovered in the systematic review was evident. Systematic reviews have been criticised for privileging RCTs over other methodologies[334]. Although they might be the best level of evidence, when few exist, other types of evidence need to be taken into consideration. Research in dysphagia is gaining ground, but there are still very few RCTs[236], partly due to a limited number of SLTs in research, but also due to dysphagia rehabilitation being a complex intervention. This systematic review aimed to include n=1 or non-controlled studies that met quality standards, but found none. These types of studies can be embedded in clinical practice and can address some of the pitfalls of larger scale RCTs [335]. Therapists often adopt interventions clinically before they have been assessed for efficacy which may be due to the perceived lack of need for rigorous preclinical safety studies as there are with drug or device trials. With a recent surge in interest and funding for clinical academic careers, these types of research studies should perhaps be encouraged but training in how to conduct them to a high standard is essential. Applying this to acute stroke may be more complicated as a series of repeated baseline measures are required to demonstrate stability in an outcome prior to commencing an intervention so its baseline can be used as a control.

The wide range of outcome measures used in studies included in the systematic review, many unvalidated, made comparison difficult. Some studies only looked at swallow physiology, whilst important to understand mechanisms behind swallowing, this may not be clinically significant or meaningful to patients. In other fields of research such as in aphasia, experts have tried to establish international consensus on a set of outcome measures recommended for use in future trials, named a core outcome set (COS)[336]. These are a minimum set of measures that should be included in all studies, but others can be added. [337]. Cohen and colleagues suggested that measures may differ for different stages of research but suggests that phase III trials will need to focus on real world dysphagia or functional outcomes [198]. Difficulties in defining a COS for post stroke dysphagia trials may arise due to lack of robust validated tools with this population, but at least it may highlight priorities for further research.

Based on the DSRS data from the RCT of strength and skill swallowing training with surface electromyographic biofeedback 450 to 500 participants are required to sufficiently power a larger study. In order to increase participant numbers without an excessively long recruitment period a multi-centre trial would need to be considered. It may be that some patients who lack demonstrable capacity to understand, weigh up and communicate the key information involved in a clinical trial, would still be able to participate in this intervention. By including patients who lack capacity it may help with recruitment rate as well as cover a wider stroke demographic. Who delivers the intervention is also important to consider in future trials. In this study recruitment was hampered by limited researcher capacity to deliver the intervention to more than two participants at any one time. By training the clinical team to deliver the intervention or having more researcher availability recruitment would increase.

Similarly, considering the content of the intervention, the treatment fidelity data demonstrated the need to alter the protocol to include the initial level of practicing repetitive swallows. It also highlighted the need to provide verbal feedback as well as visual feedback to encourage participants during challenging moments. The author who is a clinical SLT delivered the training and was able to make these judgements, but it is unclear whether non-dysphagia specialists would be able to deliver the intervention to the same degree. What training, experience and level of qualification or specialism needed to deliver the training will need to be explored prior to a larger trial. It was noted that the visual feedback with the BiSSkiT is simplistic and unstimulating. As discussed in Chapter 6 there are more game like interfaces available that could be considered, but it is not clear that they are superior as a more stimulating screen may be more difficult to process for some patients with cognitive impairment. Patient and public involvement (PPI) could also help to determine which interface may be preferable.

Little is known about the most efficacious dose of dysphagia intervention and in particular this intervention. Although not powered for efficacy this study demonstrated greater gains in swallow severity, function and safety but not significantly. A larger trial with sufficient power will detect if this dose of intervention is sufficient. Prior to a larger study, a dosing study would be beneficial to understand the optimal dose. Pairing behavioural skill and strength training with central neurostimulation to enhance neuroplasticity is another avenue that could be explored [338].

In a larger study, careful consideration will need to be given regarding a suitable control group. The dysphagia therapy provided as usual care received in this study was minimal, if this was repeated in a larger study it would be difficult to draw conclusions as to whether this

specific intervention was superior. Furthermore, this study investigated a moderately high intensity strength and skill training AND biofeedback rather than biofeedback alone. Therefore, it is unclear whether the strength and skill exercises alone are beneficial, or are superior if paired with biofeedback.

In the systematic review, the notion that interventions should target specific presentations of dysphagia was discussed. For example, in this intervention the strength training section has been shown to improve hyolaryngeal elevation and base of tongue to pharyngeal wall contraction. Thus, it could be argued that this intervention should only be offered to patients with these impairments. However, the intervention also included skill training, and little is known about what patients, or presentations of dysphagia may benefit from skill training or whether this intervention may be suitable for all types of dysphagia. Due to its theoretical underpinnings the later may well be the case. The inclusion criteria in this study did not include any specific dysphagia traits only the presence of dysphagia and although recruitment almost hit the target of 30, having a stricter very specific criteria will make recruitment even slower. Although numbers are small, a deeper analysis of the VFS data to look for patterns in impairment and whether particular subgroups responded better to therapy may help inform further research questions. A larger study which would have greater numbers of patients with hyolaryngeal elevation, tongue base to pharyngeal wall contraction could look at whether these subgroups may respond better to the intervention.

The choice of FOIS ≤5 as the cut off criteria for inclusion meant that several patients who had ongoing dysphagia requiring thickened drinks were excluded because the FOIS assesses diet only. The DSRS would be a similarly easy to score scale that has undergone rigorous validation. A cut off of ≥2 on the combined score of the diet and fluid sections would address this.

Two participants required fewer than the 10 intervention sessions because they resolved mid intervention. The intervention may have helped recovery, but it is likely that spontaneous recovery was a larger factor. Many patients with dysphagia do resolve within 2-3 weeks, therefore it may be more cost effective to aim to offer this intervention to patients who show slower recovery patterns. This could be achieved by adding 'stable dysphagia' to the inclusion criteria. Qualified by a change of less than 2 on the DSRS over a period of a week.

In order to reduce risk of bias, a larger trial will need to have assessors blinded to treatment group. Although important to consider, blinding of staff delivering the training will be impossible in this intervention.

The DHI assessment of quality of life around dysphagia which includes a patient reported outcome measure was more problematic. Despite participants having capacity to consent to the study their insight into specific aspects of their dysphagia was often impaired. These participants often answered the questions about their life prior to their stroke instead of now. This is likely to have skewed the results. The DHI is also long to administer and thus alternatives should be considered.

The PAS was also an outcome measure that is widely used, has been validated and assesses swallow safety but is less of a functional or meaningful measure for patients. Physiological measures even less so. The use of VFS made recruitment more challenging – clinic slots needed to be available and participants needed to be able to sit in a suitable chair. Videofluoroscopy practices and equipment varies around the country which can impact on the quality of the data [121]. If analysis of subtypes of dysphagia was needed in a larger study, physiological data from VFS would be required. In this case PAS could be included as an

outcome measure but conducting VFS for the PAS alone, may be inordinate and could impede recruitment.

7.5 Other wider questions arising from the research

The problems with the VFS MBSImP analysis highlighted the need for a clear definition of dysphagia from VFS and a validated tool to assess for the presence of dysphagia according to the definition. Due to the complex nature of dysphagia and the variability in normal swallowing in the population it may be that an accurate definition cannot be achieved from VFS alone. Clinically VFS is used in conjunction with bedside assessment, patient medical history and patient reports, to determine presence of dysphagia. Certainly, more normative data across the ages using the tools that have been published would help. Including data from non-dysphagic acute stroke patients especially if VFS is used as an outcome measure in clinical trials. The VFS MBSImP data for the participants in this study who presented with no clinical dysphagia according to SLTAx could be further analysed and summarised to form part of this normative data set.

7.6 Conclusions

The first part of this thesis has demonstrated that trained nurses using the DTNAx can screen acute stroke patients and identify those with dysphagia. In addition, they can make appropriate early diet and fluid recommendations for patients with mild to moderate dysphagia. Further research is needed into streamlining the tool and assessing the clinical utility and cost effectiveness of the pathway.

The second part of this thesis established that sEMG biofeedback when paired with swallow strength and skill training is feasible for acute stroke patients with dysphagia. Further research is warranted to explore delivery, dosing and efficacy.

Further gaps in the research have also been identified whilst conducting these studies. Ongoing research is needed to strengthen the validity of swallowing outcome measures, gather normative data using these measures, agree definitions of dysphagia using a range of measures and come to a consensus on core set of measures for use in clinical trials in order to compare interventions effectively.

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Appendices

Appendix 1 Dysphagia Trained Nurse Assessment form

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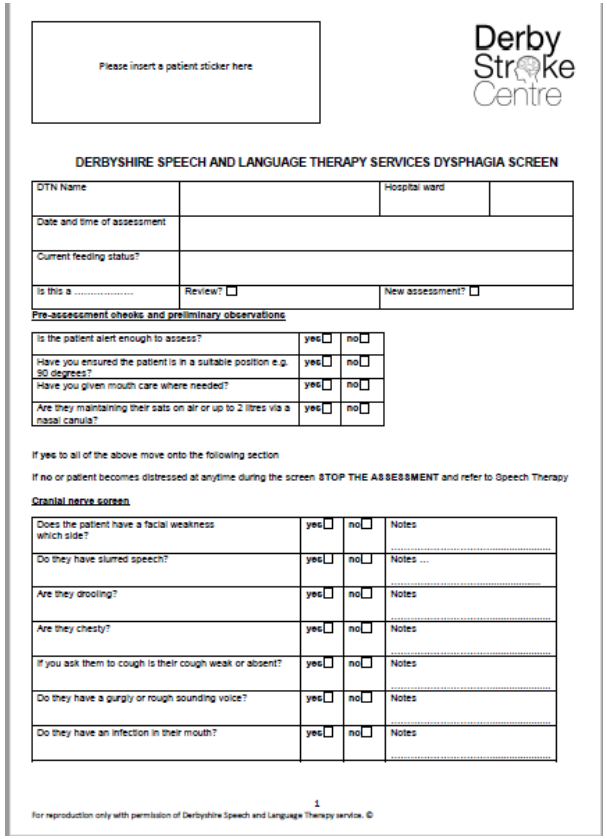

Please insert a patient sticker here

Derby Stroke Centre

DERBYSHIRE SPEECH AND LANGUAGE THERAPY SERVICES DYSPHAGIA SCREEN

DTN Name		Hospital ward	
Date and time of assessment			
Current feeding status?			
Is this a	Review? ☐	New assessment? ☐	

Pre-assessment checks and preliminary observations

Is the patient alert enough to assess?	yes☐	no☐
Have you ensured the patient is in a suitable position e.g. 90 degrees?	yes☐	no☐
Have you given mouth care where needed?	yes☐	no☐
Are they maintaining their sats on air or up to 2 litres via a nasal canula?	yes☐	no☐

If yes to all of the above move onto the following section

If no or patient becomes distressed at anytime during the screen **STOP THE ASSESSMENT** and refer to Speech Therapy

Cranial nerve screen

Does the patient have a facial weakness which side?	yes☐	no☐	Notes .....
Do they have slurred speech?	yes☐	no☐	Notes .....
Are they drooling?	yes☐	no☐	Notes .....
Are they chesty?	yes☐	no☐	Notes .....
If you ask them to cough is their cough weak or absent?	yes☐	no☐	Notes .....
Do they have a gurgly or rough sounding voice?	yes☐	no☐	Notes .....
Do they have an infection in their mouth?	yes☐	no☐	Notes .....

1

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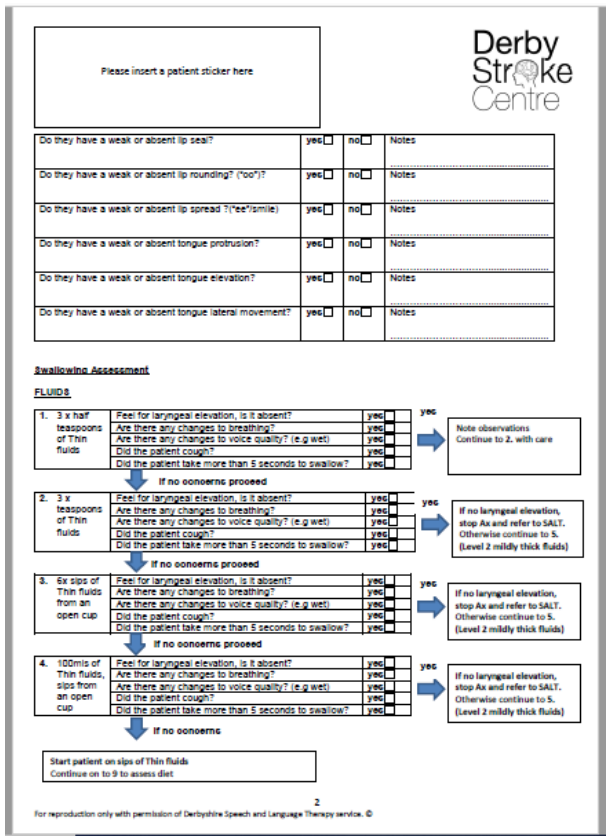


Please insert a patient sticker here

Derby Stroke Centre

Do they have a weak or absent lip seal?	yes☐	no☐	Notes .....
Do they have a weak or absent lip rounding? ("oo")?	yes☐	no☐	Notes .....
Do they have a weak or absent lip spread ?("ee"/smile)	yes☐	no☐	Notes .....
Do they have a weak or absent tongue protrusion?	yes☐	no☐	Notes .....
Do they have a weak or absent tongue elevation?	yes☐	no☐	Notes .....
Do they have a weak or absent tongue lateral movement?	yes☐	no☐	Notes .....

Swallowing Assessment

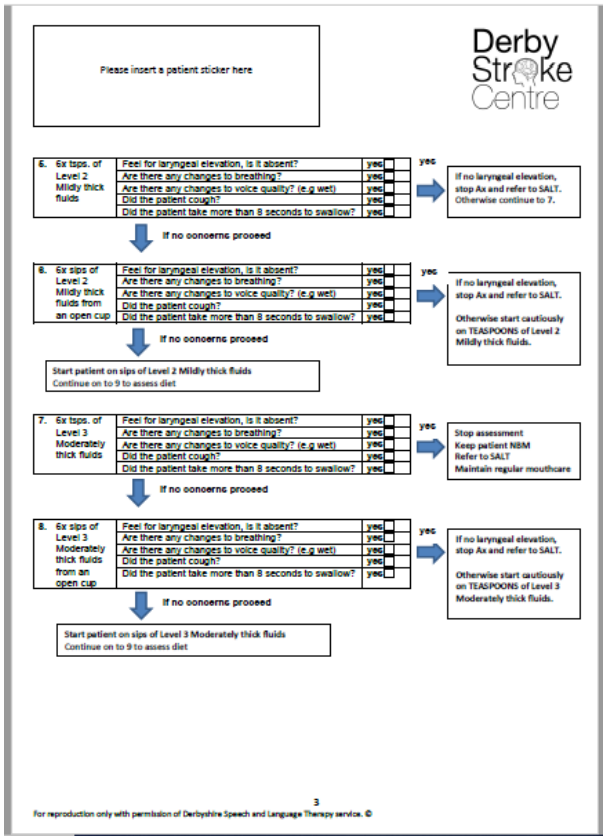
FLUIDS

1. 3 x half teaspoons of Thin fluids	Feel for laryngeal elevation, is it absent?	yes☐	yes → Note observations Continue to 2. with care
	Are there any changes to breathing?	yes☐	
	Are there any changes to voice quality? (e.g wet)	yes☐	
	Did the patient cough?	yes☐	
	Did the patient take more than 5 seconds to swallow?	yes☐	
	If no oonoerns proceed		
2. 3 x teaspoons of Thin fluids	Feel for laryngeal elevation, is it absent?	yes☐	yes → If no laryngeal elevation, stop Ax and refer to SALT. Otherwise continue to 5. (Level 2 mildly thick fluids)
	Are there any changes to breathing?	yes☐	
	Are there any changes to voice quality? (e.g wet)	yes☐	
	Did the patient cough?	yes☐	
	Did the patient take more than 5 seconds to swallow?	yes☐	
	If no oonoerns proceed		
3. 6x sips of Thin fluids from an open cup	Feel for laryngeal elevation, is it absent?	yes☐	yes → If no laryngeal elevation, stop Ax and refer to SALT. Otherwise continue to 5. (Level 2 mildly thick fluids)
	Are there any changes to breathing?	yes☐	
	Are there any changes to voice quality? (e.g wet)	yes☐	
	Did the patient cough?	yes☐	
	Did the patient take more than 5 seconds to swallow?	yes☐	
	If no oonoerns proceed		
4. 100mls of Thin fluids, sips from an open cup	Feel for laryngeal elevation, is it absent?	yes☐	yes → If no laryngeal elevation, stop Ax and refer to SALT. Otherwise continue to 5. (Level 2 mildly thick fluids)
	Are there any changes to breathing?	yes☐	
	Are there any changes to voice quality? (e.g wet)	yes☐	
	Did the patient cough?	yes☐	
	Did the patient take more than 5 seconds to swallow?	yes☐	
	If no oonoerns		

Start patient on sips of Thin fluids
Continue on to 9 to assess diet

2

Page 3/5



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Derby Stroke Centre

6. 6x tsps. of Level 2 Mildly thick fluids	Feel for laryngeal elevation, is it absent?	yes☐	yes → If no laryngeal elevation, stop Ax and refer to SALT. Otherwise continue to 7.
	Are there any changes to breathing?	yes☐	
	Are there any changes to voice quality? (e.g wet)	yes☐	
	Did the patient cough?	yes☐	
	Did the patient take more than 8 seconds to swallow?	yes☐	
	If no oonoerns proceed		
8. 6x sips of Level 2 Mildly thick fluids from an open cup	Feel for laryngeal elevation, is it absent?	yes☐	yes → If no laryngeal elevation, stop Ax and refer to SALT. Otherwise start cautiously on TEASPOONS of Level 2 Mildly thick fluids.
	Are there any changes to breathing?	yes☐	
	Are there any changes to voice quality? (e.g wet)	yes☐	
	Did the patient cough?	yes☐	
	Did the patient take more than 8 seconds to swallow?	yes☐	
	If no oonoerns proceed		

Start patient on sips of Level 2 Mildly thick fluids
Continue on to 9 to assess diet

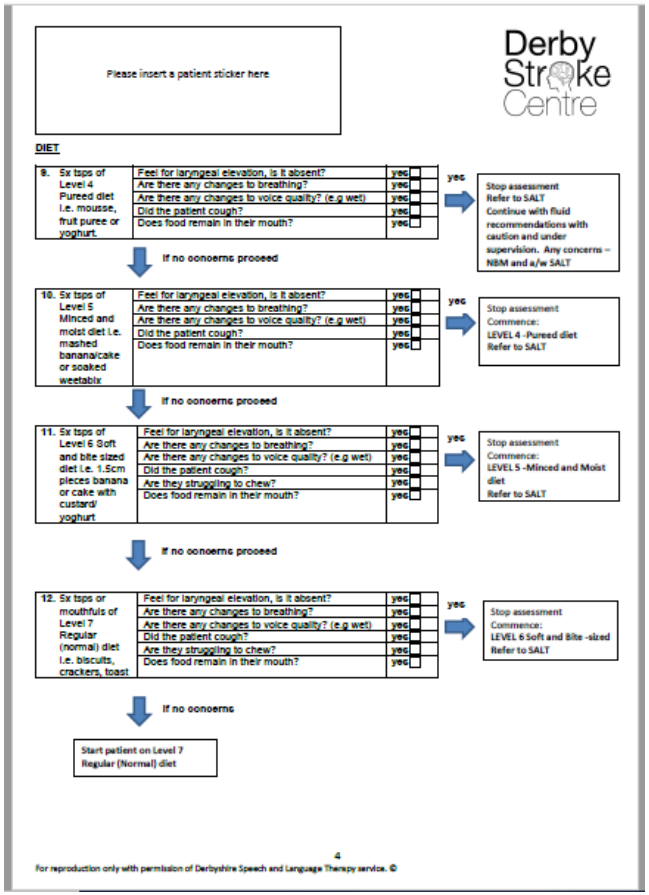
7. 6x tsps. of Level 3 Moderately thick fluids	Feel for laryngeal elevation, is it absent?	yes☐	yes → Stop assessment Keep patient NBM Refer to SALT Maintain regular mouthcare
	Are there any changes to breathing?	yes☐	
	Are there any changes to voice quality? (e.g wet)	yes☐	
	Did the patient cough?	yes☐	
	Did the patient take more than 8 seconds to swallow?	yes☐	
	If no oonoerns proceed		
8. 6x sips of Level 3 Moderately thick fluids from an open cup	Feel for laryngeal elevation, is it absent?	yes☐	yes → If no laryngeal elevation, stop Ax and refer to SALT. Otherwise start cautiously on TEASPOONS of Level 3 Moderately thick fluids.
	Are there any changes to breathing?	yes☐	
	Are there any changes to voice quality? (e.g wet)	yes☐	
	Did the patient cough?	yes☐	
	Did the patient take more than 8 seconds to swallow?	yes☐	
	If no oonoerns proceed		

Start patient on sips of Level 3 Moderately thick fluids
Continue on to 9 to assess diet

3

Page 4/5

Page 5/5



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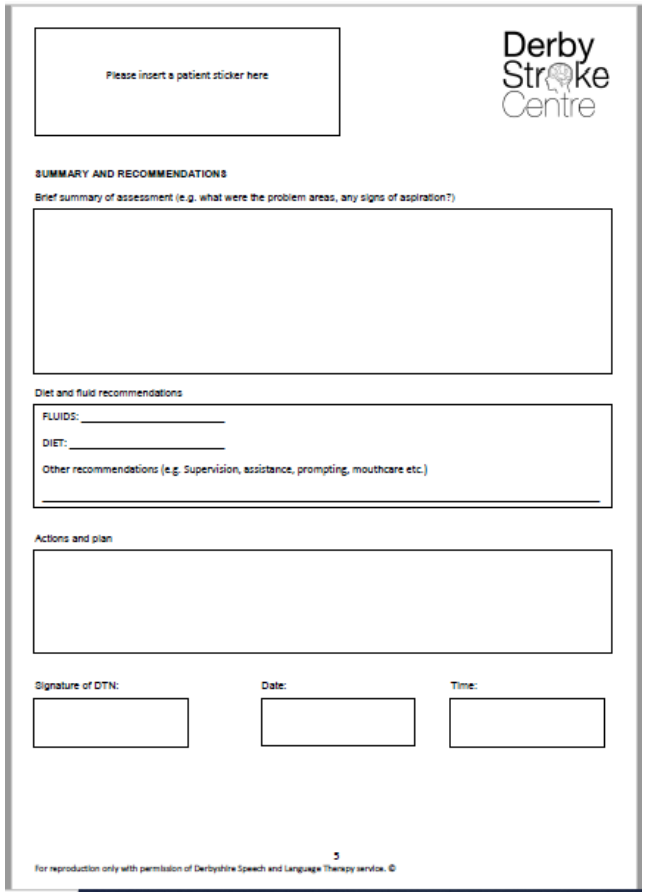
Derby Stroke Centre

DIET

9. 5x tsps of Level 4 Pureed diet i.e. mousse, fruit puree or yoghurt	Feel for laryngeal elevation, is it absent?	yes ☐	yes →	Stop assessment Refer to SALT Continue with fluid recommendations with caution and under supervision. Any concerns – NBM and a/w SALT
	Are there any changes to breathing?	yes ☐		
	Are there any changes to voice quality? (e.g wet)	yes ☐		
	Did the patient cough?	yes ☐		
	Does food remain in their mouth?	yes ☐		
↓ If no concerns proceed				
10. 5x tsps of Level 5 Minced and moist diet i.e. mashed banana/cake or soaked weetabix	Feel for laryngeal elevation, is it absent?	yes ☐	yes →	Stop assessment Commence: LEVEL 4 -Pureed diet Refer to SALT
	Are there any changes to breathing?	yes ☐		
	Are there any changes to voice quality? (e.g wet)	yes ☐		
	Did the patient cough?	yes ☐		
	Does food remain in their mouth?	yes ☐		
↓ If no concerns proceed				
11. 5x tsps of Level 6 Soft and bite sized diet i.e. 1.5cm pieces banana or cake with custard/ yoghurt	Feel for laryngeal elevation, is it absent?	yes ☐	yes →	Stop assessment Commence: LEVEL 5 -Minced and Moist diet Refer to SALT
	Are there any changes to breathing?	yes ☐		
	Are there any changes to voice quality? (e.g wet)	yes ☐		
	Did the patient cough?	yes ☐		
	Are they struggling to chew?	yes ☐		
	Does food remain in their mouth?	yes ☐		
↓ If no concerns proceed				
12. 5x tsps or mouthfuls of Level 7 Regular (normal) diet i.e. biscuits, crackers, toast	Feel for laryngeal elevation, is it absent?	yes ☐	yes →	Stop assessment Commence: LEVEL 6 Soft and Bite -sized Refer to SALT
	Are there any changes to breathing?	yes ☐		
	Are there any changes to voice quality? (e.g wet)	yes ☐		
	Did the patient cough?	yes ☐		
	Are they struggling to chew?	yes ☐		
	Does food remain in their mouth?	yes ☐		
↓ If no concerns				

Start patient on Level 7 Regular (Normal) diet

4



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Derby Stroke Centre

SUMMARY AND RECOMMENDATIONS

Brief summary of assessment (e.g. what were the problem areas, any signs of aspiration?)

Diet and fluid recommendations

FLUIDS: _____

DIET: _____

Other recommendations (e.g. Supervision, assistance, prompting, mouthcare etc.)

Actions and plan

Signature of DTN: Date: Time:

5

Appendix 2 PRISMA checklist for Systematic review and meta-analysis of comprehensive swallow screening tests

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	3
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	3
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	3 & Table 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	3
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	3
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3

Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	4
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	4
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	4

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	4 & Fig 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	4 -7 & Table 2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	8 & Table 5
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	7 – 8 Table 4
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	7 - 8 & Figure 2
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	8– 11
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	11

Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	12
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Title page

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

Appendix 3 Data extraction form

Comprehensive Screening Tests of swallowing

Data extraction Form

Assessment name

Authors and dates:

1. Complete QUADAS-2 form
2. Complete table below:

What type of validation? Construct, criterion etc.	
What was being validated for dysphagia vs aspiration?	
What are the components of the assessment?	
How long does it take to administer?	
What are the possible outcomes of the assessment?	
What was the gold standard?	
What analysis was performed in the gold standard assessment?	
Was reliability of analysis of gold standard assessed?	
Was Inter-rater reliability of the assessment tested?	
Intra-rater reliability of the assessment tested?	
Who can be trained to carry out the assessment?	
Training & competency requirements	
Where, when and how is the assessment carried out?	

Appendix 4 QUADAS 2 tool: Risk of bias and applicability judgments

Name of assessment: _____

Publication names and dates: _____

QUADAS-2 tool: Risk of bias and applicability judgments

Domain 1: Patient selection	
A. Risk of bias	
Describe methods of patient selection:	
• **Was a consecutive or random sample of patients enrolled?**	Yes/No/Unclear
• **Was a case-control design avoided?**	Yes/No/Unclear
• **Did the study avoid inappropriate exclusions?**	Yes/No/Unclear
Could the selection of patients have introduced bias?	RISK: LOW/HIGH/UNCLEAR
B. Concerns regarding applicability	
Describe included patients (prior testing, presentation, intended use of index test and setting):	
Is there concern that the included patients do not match the review question?	CONCERN: LOW/HIGH/UNCLEAR
Domain 2: Index test(s) ***(if more than 1 index test was used, please complete for each test)***	
A. Risk of bias	
Describe the index test and how it was conducted and interpreted:	
• **Were the index test results interpreted without knowledge of the results of the reference standard?**	Yes/No/Unclear
• **If a threshold was used, was it pre-specified?**	Yes/No/Unclear
Could the conduct or interpretation of the index test have introduced bias?	RISK: LOW/HIGH/UNCLEAR
B. Concerns regarding applicability	
Is there concern that the index test, its conduct, or interpretation differ from the review question?	CONCERN: LOW/HIGH/UNCLEAR
Domain 3: Reference standard	
A. Risk of bias	
Describe the reference standard and how it was conducted and interpreted:	

• **Is the reference standard likely to correctly classify the target condition?**	Yes/No/Unclear
• **Were the reference standard results interpreted without knowledge of the results of the index test?**	Yes/No/Unclear
Could the reference standard, its conduct, or its interpretation have introduced bias?	RISK: LOW/HIGH/UNCLEAR
B. Concerns regarding applicability	
Is there concern that the target condition as defined by the reference standard does not match the review question?	CONCERN: LOW/HIGH/UNCLEAR
Domain 4: Flow and timing	
A. Risk of bias	
Describe any patients who did not receive the index test(s) and/or reference standard or who were excluded from the 2x2 table (refer to flow diagram):	
Describe the time interval and any interventions between index test(s) and reference standard:	
• **Was there an appropriate interval between index test(s) and reference standard?**	Yes/No/Unclear
• **Did all patients receive a reference standard?**	Yes/No/Unclear
• **Did patients receive the same reference standard?**	Yes/No/Unclear
• **Were all patients included in the analysis?**	Yes/No/Unclear
Could the patient flow have introduced bias?	RISK: LOW/HIGH/UNCLEAR

Appendix 5 Patient information sheets: **The accuracy of the Dysphagia Trained Nurse Assessment in Acute Stroke**

University of Nottingham, School of Medicine
Queen's Medical Centre
Nottingham
NG7 2UH

Patient Information Sheet. Final Version 1.3, 9th April 2018

Nurse assessments of swallowing in acute stroke

You have been invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish to. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part or not. If you decide to take part you may keep this leaflet. Thank you for reading this.

What is the research?

Stroke can affect a person's ability to swallow food and drinks safely. National stroke guidelines state that all patients who have had a stroke should have their swallowing assessed within 4 hours. In the stroke unit in Derby we have a number of nurses trained to carry out swallowing assessments. If patients are found to have swallowing difficulties they are referred for further assessment and ongoing input from the speech and language therapists. It has been working this way for many years. This research study aims to show scientifically how good the screening assessment is at identifying patients with swallowing difficulties.

What does it involve?

You will have had an initial assessment by one of the nurses following your admission. The researchers will gather some information about your stroke and health. The research study will involve you participating in a series of further swallowing assessments over 24 hours:

- Re-assessment by the same and/or a different nurse
  The nurse will do a brief assessment of the swallowing muscles in your mouth and throat. They will then give you small amounts of drinks and food and observe how you swallow. From this

they can recommend if you can start eating and drinking and what foods/drinks are the most appropriate. This will take less than 20 minutes.

- Assessment of your swallowing at bedside by the speech and language therapist
  One of the ward speech and language therapist will assess your swallowing in a similar way. This will take less than 30 minutes.
- Videofluoroscopy –it is possible that you will have an assessment of your swallow using video X-ray. You will be taken down to the xray department. During the assessment you will sit in a chair in the video x-ray images will be recorded whilst you are given small amounts of food/drinks. The food/drinks will be mixed with a small amount of barium which makes them show up on the xray. This does not alter the taste of the food/drinks but some people find they can be a little chalky. You will be away from the ward for less than 50 minutes and in the x-ray room for approximately 10 minutes. If you are unable to sit out in a chair you will not have this assessment.

Where?

The swallowing assessments will be carried out at your bedside by the nurse or speech and language therapist. The videofluoroscopy will be carried out in the X-ray department.

Why have you been chosen?

You have been chosen because you have had a new stroke. You may or may not have swallowing difficulties. This is because we are aiming to find

- 25 patients who have swallowing difficulties and
- 25 patients who do not have swallowing difficulties

This is so we can check that everybody is represented and thus determine how good the assessment tool is.

Do you have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What are the possible benefits of taking part?

You will have a thorough examination of your swallowing and will be given the most appropriate recommendations about the safest foods and drinks for you.

What are the possible disadvantages and risks of taking part?

If you take part in this study you may have a Videofluoroscopy, or video x-ray. This may be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your swallowing and provide your speech therapist with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. We are all at risk of developing cancer during our lifetime due to radiation occurring naturally in the background. Taking part in this study will only increase this risk by a small amount - the amount of radiation from the videofluoroscopy is about 9-times less than the amount of radiation we are exposed to from background radiation per year.

Expenses and payments

Participants will not be paid to participate in the study.

What if something goes wrong?

In case you have a complaint on your treatment by a member of staff or anything to do with the study, you can initially approach the lead investigator. If this achieves no satisfactory outcome, you should then contact Hospital Complaints Department (PALS), Tel 01332 785156

Will my taking part in this study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Dr Tim England) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for 1 year after the end of the study so that we are able to contact you about the findings of the study *and* possible follow-up studies. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of

securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

We are also asking for your consent to store and use your videofluoroscopy in possible future research. The videofluoroscopy images and the information gathered about you will be stored by the University of Nottingham at the Royal Derby Hospital, for possible use in future studies. Any samples or data used will be anonymised, and you will not be identified in any way.

Involvement of the Medical team?

If you agree to participate in this study a copy of your signed consent form will be filed in your medical records therefore your hospital medical team will be aware that you have agreed to participate in this study.

What will happen to the results of the research study?

The results will form part of a PhD (postgraduate degree) thesis and it is likely that the research will be written up for submission to a journal. There will be no identifying information about any participants in any publications. The results will be shared with other stroke professionals with the hope that it will contribute to the wider understanding about screening assessments after stroke.

Who is organising and funding the research?

The research is funded by the NIHR Collaboration for Leadership in Applied Health Research and Care East Midlands (CLAHRC EM).

The research is sponsored by the University of Nottingham.

Who has reviewed the study?

This study has been reviewed and approved by the West Midlands - Coventry & Warwickshire Research Ethics Committee.

Contact for Further Information

If you require any further information regarding this study please contact:

- Jacqui Benfield, Speech and Language Therapist/Postgraduate Researcher
  Tel: 0773 8017966. Email: jacqueline.benfield@nottingham.ac.uk
  Or ask the nurses on the ward to contact me on your behalf

Thank you for taking part in the study.

University of Nottingham
School of Medicine
Queen's Medical Centre
Nottingham
NG7 2UH

Nurse assessments of swallowing in acute stroke

Research – Swallowing – Assessment

Can you help? Here is some information …..

Stroke ….

…..can cause problems swallowing

Why do the research?

Nurses assess swallowing

We want to check the nurse assessment is accurate

Where? Here – Royal Derby Hospital

Who? Speech and Language Therapists

Nurses

What does it involve?

ASSESSMENT

Health

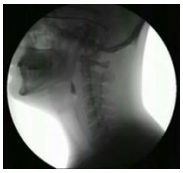
Bedside swallow assessment

Speech Therapist

Nurse

Then compare to other assessments …

Videofluoroscopy



In the X-ray department

Why have you been chosen?

You have had a stroke

Swallow problems?

Your nurse tested your swallowing – you have

☐ **No swallowing problems**

☐ **Swallowing problems**

NO

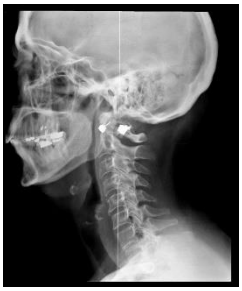
YES

You can choose to participate ….

You can stop at any time

Risks?

Very Low risk from …



Xray

What if something goes wrong?

If you are unhappy

Tell me!

If you are still unhappy

CONTACT:

Hospital Complaints Department

Tel 01332 785156

Will my taking part in this study be kept confidential?

What will happen to the results of the research study?

Send you a summary

Publish results

Present at conferences

Who is organising and funding the research?

NHS
National Institute for Health Research

Collaboration for Leadership in Applied Health Research and Care East Midlands

Who has reviewed the study?

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Contact for Further Information

If you require any further information regarding this study please contact:

Jacqui Benfield,

Speech and Language Therapist

Postgraduate Researcher

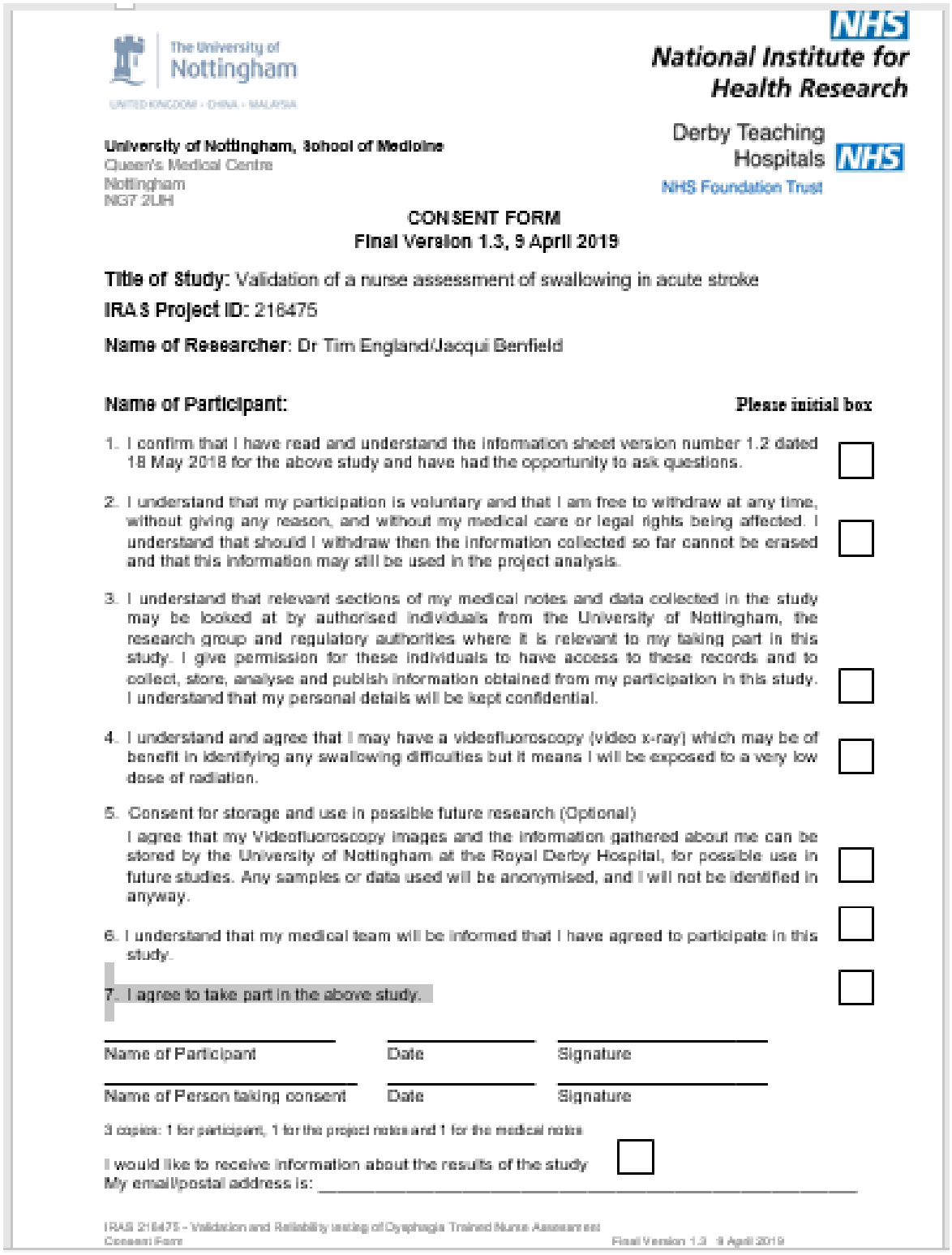
Tel: 0773 8017966.

jacqueline.benfield@nottingham.ac.uk

Or ask the nurses on the ward to contact me on your behalf

Thank you for taking part in the study

Appendix 6 Consent forms – The accuracy of the DTNAx in acute stroke



The University of Nottingham
UNITED KINGDOM • CHINA • MALAYSIA

NHS
National Institute for Health Research

Derby Teaching Hospitals NHS
NHS Foundation Trust

University of Nottingham, School of Medicine
Queen's Medical Centre
Nottingham
NG7 2UH

CONSENT FORM
Final Version 1.3, 9 April 2019

Title of Study: Validation of a nurse assessment of swallowing in acute stroke

IRAS Project ID: 216475

Name of Researcher: Dr Tim England/Jacqui Benfield

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number 1.2 dated 18 May 2018 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand and agree that I may have a videofluoroscopy (video x-ray) which may be of benefit in identifying any swallowing difficulties but it means I will be exposed to a very low dose of radiation. ☐
5. Consent for storage and use in possible future research (Optional)
   I agree that my Videofluoroscopy images and the information gathered about me can be stored by the University of Nottingham at the Royal Derby Hospital, for possible use in future studies. Any samples or data used will be anonymised, and I will not be identified in anyway. ☐
6. I understand that my medical team will be informed that I have agreed to participate in this study. ☐
7. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

I would like to receive information about the results of the study ☐
My email/postal address is: _____

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

NHS
National Institute for Health Research

University of Nottingham, School of Medicine
Queen's Medical Centre
Nottingham
NG7 2UH

Derby Teaching Hospitals NHS
NHS Foundation Trust

CONSULTEE DECLARATION FORM

Final Version 1.2, 18 May 2015

Title of Project: Validation of a nurse assessment of swallowing in acute stroke

Name of Researcher: 216475

Name of Participant: _____

Participant ID: _____

Please initial box

I _____ have been consulted about _____'s participation in this research project. I have had the opportunity to ask questions about the study and understand what is involved. ☐

In my opinion he/she would have no objection to taking part in the above study. ☐

I understand that I can request he/she is withdrawn from the study at any time, without giving any reason and without his/her care or legal rights being affected. ☐

I understand that relevant sections of his/her care record and data collected during the study may be looked at by responsible individuals from [name of sponsor and/or host organisation] or from regulatory authorities, where it is relevant to their taking part in this research. ☐

I agree to their hospital medical team being informed of their participation in the study. ☐

_____	_____	_____
Name of Consultee	Date	Signature

Relationship to participant:

_____	_____	_____

Person undertaking consultation (if different from researcher):

Name	Date	Signature
_____	_____	_____
Researcher	Date	Signature

When completed: 1 (original) to be kept in care record, 1 for consultee; 1 for researcher site file

I would like to receive information about the results of the study ☐
My email/postal address is: _____

Appendix 7 STARD CRITERIA Diagnostic accuracy of the Dysphagia Trained Nurse Assessment tool in acute stroke

Section & Topic	No	Item	Reported on page #
TITLE OR ABSTRACT			
	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	2
ABSTRACT			
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	2
INTRODUCTION			
	3	Scientific and clinical background, including the intended use and clinical role of the index test	4
	4	Study objectives and hypotheses	5
METHODS			
Study design	**5**	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	6
Participants	**6**	Eligibility criteria	6
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	6
	8	Where and when potentially eligible participants were identified (setting, location and dates)	6
	9	Whether participants formed a consecutive, random or convenience series	6
Test methods	**10a**	Index test, in sufficient detail to allow replication	6-7
	10b	Reference standard, in sufficient detail to allow replication	7-8
	11	Rationale for choosing the reference standard (if alternatives exist)	7-8
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	7-8
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	6-7

	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	7-8
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	7-8
Analysis	**14**	Methods for estimating or comparing measures of diagnostic accuracy	8-9
	15	How indeterminate index test or reference standard results were handled	9
	16	How missing data on the index test and reference standard were handled	9
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	6 & 8-9
	18	Intended sample size and how it was determined	6
RESULTS			
Participants	**19**	Flow of participants, using a diagram	Table 2
	20	Baseline demographic and clinical characteristics of participants	Table 1
	21a	Distribution of severity of disease in those with the target condition	10
	21b	Distribution of alternative diagnoses in those without the target condition	n/a
	22	Time interval and any clinical interventions between index test and reference standard	Table 2
Test results	**23**	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	Tables 3-5
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Tables 3-5
	25	Any adverse events from performing the index test or the reference standard	n/a
DISCUSSION			
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	17
	27	Implications for practice, including the intended use and clinical role of the index test	13-17
OTHER INFORMATION			
	28	Registration number and name of registry	2
	29	Where the full study protocol can be accessed	6
	30	Sources of funding and other support; role of funders	18

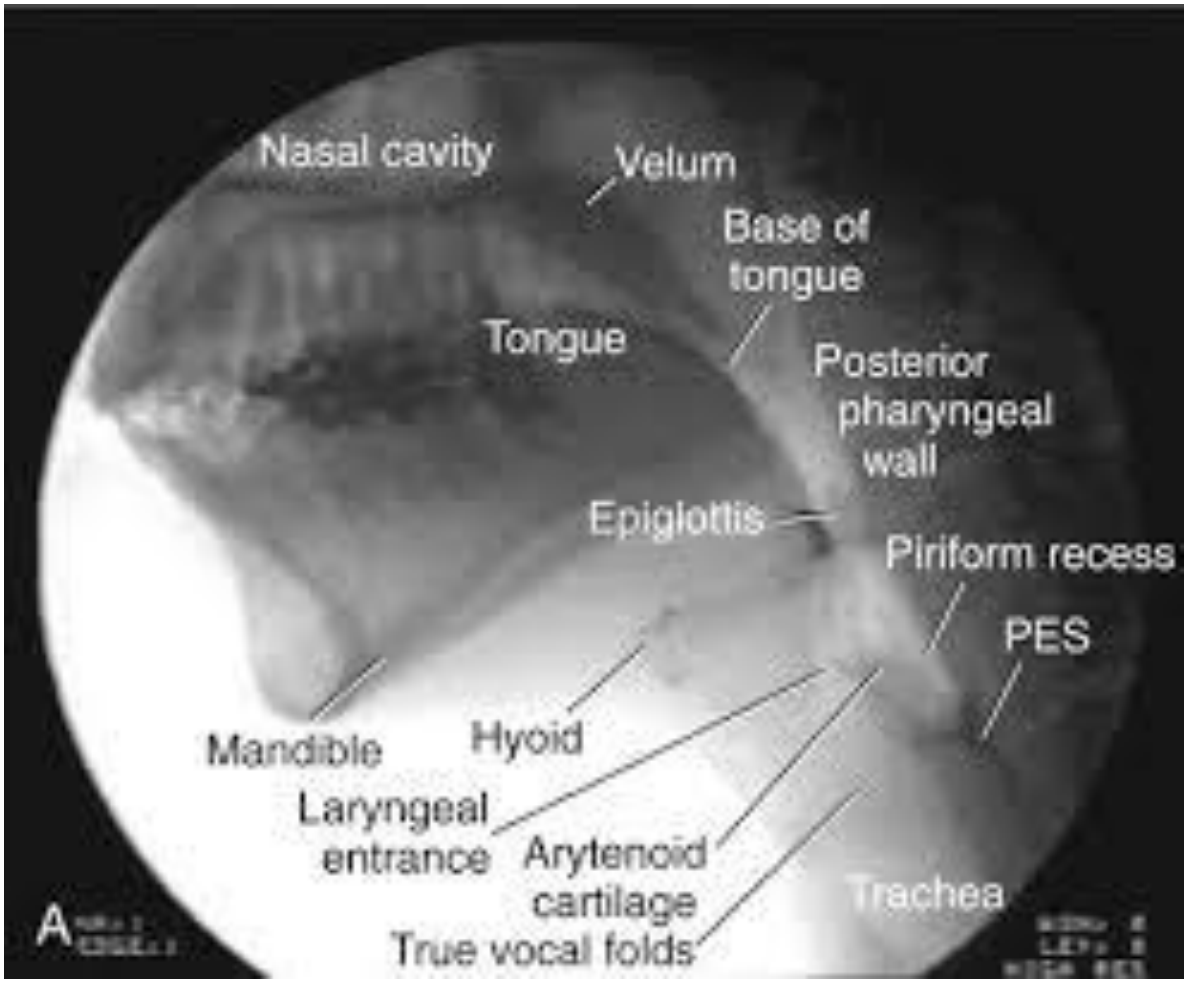
VIDEOFLUOROSCOPY RESEARCH PROTOCOL

Information for Radiologists & Radiographers

The speech and language therapist will use a standard protocol for the assessment

The oral cavity, velum, pharynx, larynx and cricopharyngeal segment need to be in frame

Start screening when the bolus enters the mouth until after the swallow **AND** any clearing swallows



Appendix 9 Dysphagia Severity Rating Scale

Score	Fluids	Score	Diet	Score	Supervision
4	No oral fluids	4	Non oral feeding	4	No oral feeding
3	IDDSI Level 4	3	IDDSI Level 4 & 5	3	Therapeutic feeding (SALT/trained staff)
2	IDDSI Level 3	2	IDDSI Level 6	2	Feeding by third party (untrained)
1	IDDSI Level 1 & 2	1	IDDSI Level 7 easy chew	1	Eating with supervision
0	IDDSI Level 0	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* fluids or trials of food *and* fluids.

Appendix 10 Participant Information Sheet – Nurse Interviews

University of Nottingham, School of Medicine
Queen's Medical Centre
Nottingham
NG7 2UH

Nurse Information Sheet. Version 1.2, 08 February 2019
Dysphagia Trained Nurse assessment of swallowing in acute stroke
Name of chief investigator: Dr Tim England
IRAS Project ID: 216475

You have been invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your colleagues if you wish to. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part or not. If you decide to take part you may keep this leaflet. Thank you for reading this.

What is the research?

National stroke guidelines state that all patients who have had a stroke should have their swallowing assessed within 4 hours. You are one of the many nurses trained to carry out swallowing assessments in the stroke unit in Derby using the Dysphagia Trained Nurse (DTN) Assessment tool. It has been working well this way for many years. We are currently conducting a research project to confirm scientifically how good the screening assessment is at identifying patients with dysphagia. Alongside this we want to determine the thoughts and experiences of the Dysphagia Trained Nurses who assess patients regularly using the tool. This is so we can determine how the DTN role is perceived, the level of usability of the DTN tool and the adequacy of the training.

What does it involve?

You will also be invited to be interviewed and asked to answer a series of questions about the DTN training, what you think of the assessment tool and how the DTN role works on the ward. This will not take more than about 15 minutes. The interview will be audio recorded with permission so that it can be analysed. The interview will be transcribed by one of the research team and any identifying information will be removed during this transcription.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Your employment should not be effected whether you do or do not take part.

What are the possible disadvantages and risks of taking part?

If there are any training needs identified as a result of the study or any other concerns in relation to professional practice, this will be discussed. Further training will be provided.

What are the possible benefits of taking part?

The collective feedback from yourselves about the DTN system may be used to identify and address any concerns or challenges you might have.

Expenses and payments

Participants will not be paid to participate in the study.

Will my taking part in this study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

All information which is collected about you during the course of the research including the audio recording will be kept strictly confidential, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for 1 year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

What will happen to the results of the research study?

The results will form part of a PhD thesis and it is likely that the research will be written up for submission to a journal. There will be no identifying information about any participants in any publications.

Who is organising and funding the research?

The research is funded by the NIHR Collaboration for Leadership in Applied Health Research and Care East Midlands (CLAHRC EM).

The research is sponsored by the University of Nottingham.

Who has reviewed the study?

This study has been reviewed and approved by the NHS Ethics committees.

Contact for Further Information

If you require any further information regarding this study please contact:

- Jacqui Benfield, Speech and Language Therapist/Postgraduate Researcher
  Tel: 0773 8017966. Email: jacqueline.benfield@nottingham.ac.uk
  Or ask the nurses on the ward to contact me on your behalf

Thank you for taking part in the study.

National Institute for Health Research

University of Nottingham, School of Medicine
Queen's Medical Centre
Nottingham
NG7 2UH

CONSENT FORM
Final Version 1.2, 18 February 2019

Title of Study: Dysphagia Trained Nurse assessment of swallowing in acute stroke

IRAS Project ID: 216475

Name of Researcher: Dr Tim England/Jacqui Benfield

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number 1.2 dated 8th February 2019 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that the interview will be recorded and transcribed and that anonymous direct quotes from the interview may be used in the study reports. ☐

4. I understand that relevant sections of my data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Appendix 12 COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of nonparticipants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	

Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	
Topic	**Item No.**	**Guide Questions/Description**	**Reported on Page No.**
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Appendix 13 Biofeedback Systematic Review - Data Extraction form

Biofeedback Systematic Review - Data Extraction form

Name of reviewer		
Date of review		
Study Title		
Study ID		
Eligibility criteria	Diagnosis of dysphagia secondary to any cause	
	Age ≥18 years	
	Measure of dysphagia recorded pre and post therapy	
	OR Measure of clinical outcomes recorded pre and post therapy	
	Articles in English language	
	Full articles available for review	
	Dysphagia therapy includes biofeedback	
	Details of intervention documented for replicability	
Meets criteria to be accepted?		
Study type: RCT, Case control, single case etc.		
Participants; number and dysphagia type/cause, inpatient, outpatient, acute, chronic, control group participants etc		
Methods: intervention; type, intensity, control group intervention		
Outcomes; outcome measure and outcome scores		
Other Notes		
Risk of Bias – in groups with control group	**Is it an RCT?**	
Bias	**Details**	**Authors' judgement of bias – High or Low**
Random sequence generation? (selection bias)		
Allocation concealment? (selection bias)		

Blinding of participants and personnel (performance bias) All outcomes?			
Blinding of outcome assessment (detection bias) All outcomes?			
Incomplete outcome data? (detection bias) All outcomes?			
Selective reporting? (reporting bias)			
Risk of bias - studies with no control group			**If YES = Good quality, If NO = Poor quality. Authors judgement of risk of bias – High or Low**
AB design (A=no treatment, B= treatment)		How many data points? Are there at least 5 reported baseline data points?	
Was a more complex design used to identify treatment effect?	Multiple baselines	If N>1 did the intervention start at different time points for different individuals?	
	Alternating treatments	Were alternating treatments used? i.e. ABAC	
	Alternating intensity	Were different levels of intensity used? i.e. AB1B2B3.	
Analysis (detection bias)		Was the data analysis appropriate? i.e. 2 sd band method, celeration line, C-statistic	
Replicability		Has this been repeated with another individual/group	
Generalisability		Was/were the individual(s) representative of a clinical population?	
Blinding of participants/therapists? (performance bias)		Were the participants blinded?	
Blinding of assessors (detection and performance bias)		Were any of the assessors independent?	
Incomplete outcome data? (detection bias) All outcomes?			
Selective reporting? (reporting bias)			

Name of second reviewer	
Date of review	
Do you agree with data extraction/risk of bias judgements? Yes/No	
If not, please give details of each disagreement and why	

Appendix 14 Criteria for assessing risk of bias

For studies with control groups:	
Bias	**Details**
Random sequence generation? (selection bias) http://handbook.cochrane.org/chapter_8.htm	*There is a low risk of selection bias* if the investigators describe a random component in the sequence generation process such as*:* referring to a random number table, using a computer random number generator, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots, minimization (minimization may be implemented without a random element, and this is considered to be equivalent to being random). *There is a high risk of selection bias* if the investigators describe a non-random component in the sequence generation process, such as: sequence generated by odd or even date of birth, date (or day) of admission, hospital or clinic record number; or allocation by judgement of the clinician, preference of the participant, results of a laboratory test or a series of tests, or availability of the intervention.
Allocation concealment? (selection bias) http://handbook.cochrane.org/chapter_8.htm	*There is a low risk of selection bias* if the participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomization); sequentially numbered drug containers of identical appearance; or sequentially numbered, opaque, sealed envelopes. *There is a high risk of bias* if participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; or other explicitly unconcealed procedures.
Blinding of participants and personnel (performance bias) **All outcomes?** http://handbook.cochrane.org/chapter_8.htm	*There is a low risk of performance bias* if blinding of participants or personnel was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding. *High risk* if not
Blinding of outcome assessment (detection bias)	*There is low risk of detection bias* if the blinding of the outcome assessment was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete

All outcomes? http://handbook.cochrane.org/chapter_8.htm	blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.; or: • *for patient-reported outcomes* in which the patient was the outcome assessor (e.g., pain, disability): *there is a low risk of bias* for outcome assessors if there is a low risk of bias for participant blinding.* • *for outcome criteria that are clinical or therapeutic events* that will be determined by the interaction between patients and care providers (e.g., co-interventions, length of hospitalization, treatment failure), in which the care provider is the outcome assessor: *there is a low risk of bias* for outcome assessors if there is a low risk of bias for care providers.* • *for outcome criteria that are assessed from data from medical forms*: *there is a low risk of bias* if the treatment or adverse effects of the treatment could not be noticed in the extracted data.*
Incomplete outcome data? (detection bias) **All outcomes?** http://handbook.cochrane.org/chapter_8.htm	*There is a low risk of attrition bias* if there were no missing outcome data; reasons for missing outcome data were unlikely to be related to the true outcome (for survival data, censoring unlikely to be introducing bias); missing outcome data were balanced in numbers, with similar reasons for missing data across groups**; for dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk was not enough to have a clinically relevant impact on the intervention effect estimate; for continuous outcome data, the plausible effect size (difference in means or standardized difference in means) among missing outcomes was not enough to have a clinically relevant impact on observed effect size, or missing data were imputed using appropriate methods. (*Note:* if drop-outs are very large, imputation using even "acceptable" methods may still suggest a high risk of bias)# **The percentage of withdrawals and drop-outs should not exceed 20% for short-term follow-up and 30% for long-term follow-up and should not lead to substantial bias. (*Note:* these percentages are commonly used but arbitrary, not supported by literature)#
Selective reporting? (reporting bias) http://handbook.cochrane.org/chapter_8.htm	*There is low risk of reporting bias* if the study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way, or if the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon). *There is a high risk of reporting bias if* not all of the study's pre-specified primary outcomes have been reported; one or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; one or more reported primary

	outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; the study report fails to include results for a key outcome that would be expected to have been reported for such a study.
For studies with no control group	
Bias	**Details**
Design for AB study Graham et al 2012 Small Sample Research Designs for Evidence-based Rehabilitation: Issues and Methods. Arch Phys Med Rehabil. 2012 August ; 93(8 Suppl): S111–S116	*Good quality* If there are 5 or more baseline measures per subject prior to the intervention. *Poor quality* If there are fewer than 5 baseline measures per subject
Use of a more robust design? Graham et al 2012 Small Sample Research Designs for Evidence-based Rehabilitation: Issues and Methods. Arch Phys Med Rehabil. 2012 August ; 93(8 Suppl): S111–S116	*Good quality* If one of the following designs are used: Multiple baselines, Alternating treatments, Alternating intensity *Poor quality* if no such design used
Analysis Graham et al 2012 Small Sample Research Designs for Evidence-based Rehabilitation: Issues and Methods. Arch Phys Med Rehabil. 2012 August ; 93(8 Suppl): S111–S116	*Good quality* if the data were analysed by one of the following methods: 2 sd band method, celeration line, C-statistic, standardized mean difference approach, regression based approaches, and visual-based approaches *Poor quality* if only common statistical techniques such as t-tests and analysis of variance ANOVA are used for analysis
Replicability Chambless, D. L. and Hollon, S. D. 1998. Defining empirically supported therapies. Journal of Consulting and Clinical Psychology, 66(1): 7–18.	*Good quality* if it has proved beneficial to at least 3 participants in research? *Poor quality* if it has only been proved to be beneficial in less than 3.
Generalisability Chambless, D. L. and Hollon, S. D. 1998. Defining empirically supported therapies. Journal of Consulting and Clinical Psychology, 66(1): 7–18.	*Good quality* studies that reproduce conditions found in actual clinical practice, that include subjects that are representative of a clinical population Poor quality for generalisability are studies that are not practical for clinical practice and where patients are not representative of a clinical population.
Both RCTs and non RCTS	
Bias	**Details**
Blinding participants/therapists http://handbook.cochrane.org/chapter_8.htm	*There is a low risk of performance bias* if blinding of participants or personnel was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.

	High risk if not
Blinding of assessors http://handbook.cochrane.org/chapter_8.htm	*There is low risk of detection bias* if the blinding of the outcome assessment was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.; or: *for patient-reported outcomes* in which the patient was the outcome assessor (e.g., pain, disability): *there is a low risk of bias* for outcome assessors if there is a low risk of bias for participant blinding. *for outcome criteria that are clinical or therapeutic events* that will be determined by the interaction between patients and care providers (e.g., co-interventions, length of hospitalization, treatment failure), in which the care provider is the outcome assessor: *there is a low risk of bias* for outcome assessors if there is a low risk of bias for care providers. *for outcome criteria that are assessed from data from medical forms*: *there is a low risk of bias* if the treatment or adverse effects of the treatment could not be noticed in the extracted data.
Incomplete outcome data? (detection bias) All outcomes? http://handbook.cochrane.org/chapter_8.htm	*There is a low risk of attrition bias* if there were no missing outcome data; reasons for missing outcome data were unlikely to be related to the true outcome (for survival data, censoring unlikely to be introducing bias); missing outcome data were balanced in numbers, with similar reasons for missing data across groups**; for dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk was not enough to have a clinically relevant impact on the intervention effect estimate; for continuous outcome data, the plausible effect size (difference in means or standardized difference in means) among missing outcomes was not enough to have a clinically relevant impact on observed effect size, or missing data were imputed using appropriate methods. (*Note:* if drop-outs are very large, imputation using even "acceptable" methods may still suggest a high risk of bias) **The percentage of withdrawals and drop-outs should not exceed 20% for short-term follow-up and 30% for long-term follow-up and should not lead to substantial bias. (*Note:* these percentages are commonly used but arbitrary, not supported by literature)
Selective reporting? (reporting bias) http://handbook.cochrane.org/chapter_8.htm	*There is low risk of reporting bias* if the study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way, or if the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

	There is a high risk of reporting bias if not all of the study's pre-specified primary outcomes have been reported; one or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; one or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; the study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Appendix 15 PRISMA Checklist A systematic review and meta-analysis of biofeedback in dysphagia therapy

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1-2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	3
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	3
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	3-4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Figure 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3-4

Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	4
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	4-5
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	4-5
Section/topic	**#**	**Checklist item**	**Reported on page #**
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	4-5
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	4-5
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 2
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	5-9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Table 2
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	9-10 & Figure 3
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	9-10
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	9-10
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	10-13
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	13
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13-14
FUNDING			

Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Title page

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

Appendix 16 Functional Oral Intake Scale

TUBE DEPENDENT (levels 1-3)

1 No oral intake
2 Tube dependent with minimal/inconsistent oral intake
3 Tube supplements with consistent oral intake

TOTAL ORAL INTAKE (levels 4-7)

4 Total oral intake of a single consistency
5 Total oral intake of multiple consistencies requiring special preparation
6 Total oral intake with no special preparation, but must avoid specific foods or liquid items
7 Total oral intake with no restrictions

Appendix 17 Patient Information Sheets – Feasibility RCT of swallow therapy with biofeedback

University of Nottingham, School of Medicine
Queen's Medical Centre
Nottingham
NG7 2UH

Patient Information Sheet
Final Version 1.2
18th May 2018

Does swallow therapy with feedback in the early stages after stroke improve swallowing?

You have been invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish to. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part or not. If you decide to take part you may keep this leaflet. Thank you for reading this.

What is the research?

Swallowing therapy has shown to help patients improve their swallowing after a stroke. We would like to find out whether swallowing therapy with visual feedback helps improve patient's swallowing more than usual therapy. We would also like to know whether swallow therapy with feedback can feasibly be delivered in hospital so soon after a stroke.

Why have you been chosen?

You have been chosen because you have difficulties swallowing as a result of a new stroke. We are looking for 30 people in total.

Do you have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What does it involve?

Assessment

The first stage will be assessing your swallowing and health. This will involve:

- Videofluoroscopy – an assessment of your swallowing using video xray in the X-ray department. A porter will collect you from the ward and take you to xray. You may be away from the ward for approximately 50 minutes but you will only be in the xray room for approximately 20 minutes.

- Assessment of your swallowing at bedside by the speech and language therapist – this will take 30 minutes maximum
- A questionnaire about how you feel about your swallowing difficulties – this will take about 15 minutes
- The researchers gathering information about your health since your stroke – this will take about 10-15 minutes.

Usual care during the research period

- As long as you need it you will be under the care of a speech and language therapist
- Your swallowing will be assessed and reviewed as usual
- The speech and language therapist will make recommendations about what you are safe to eat and drink

Therapy

To check whether this specific therapy is beneficial we need to compare it to the care that people with swallowing difficulties usually get. You will be randomly assigned to one of two groups. The groups are selected by a computer which has no information about the individual – i.e. by chance. You will randomly be assigned to one of the two following groups:

1. Feedback group – During sessions the researcher will secure a cushioned pad underneath your chin to measure your swallowing muscles. You will be able to see a line on the computer screen which will move when you swallow. You will be taught how to use this information from the screen to alter the strength and timing of your swallow. You may also do other swallowing exercises with your usual speech and language therapist or be asked to carry out exercises on your own. Over 2 weeks you will receive 2-10 sessions

2. Usual therapy group – Over 2 weeks your usual speech and language therapist will continue to review your swallowing, make recommendations about your eating and drinking and if appropriate they may practice swallowing exercises with you. You may also be asked to carry out some exercises on your own.

<u>Re-assessment</u>

After the therapy we will need to repeat the following assessments:

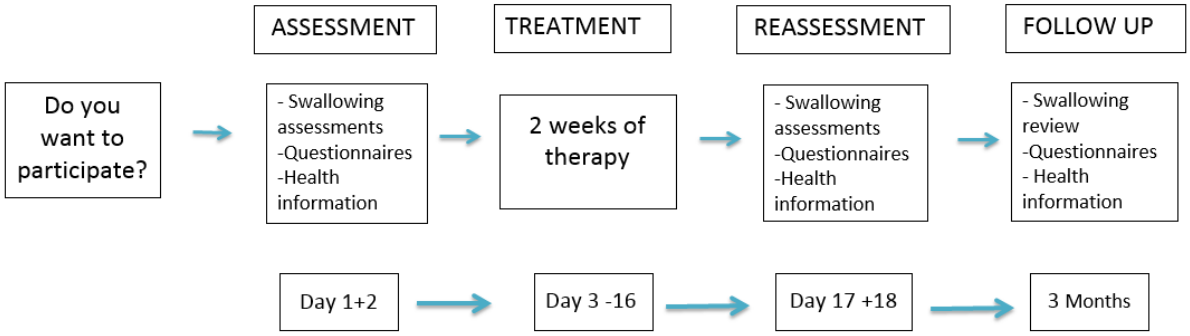
- Videofluoroscopy – an assessment of your swallowing using video xray in the X-ray department
- Assessment of your swallowing at bedside by the speech and language therapist
- A questionnaire about how you feel about your swallowing difficulties
- The researchers will gather information about your health since your stroke
- Additionally, if your received the feedback therapy you will be asked to complete a questionnaire about how you felt about the therapy

<u>At 3 months</u>

We will visit you at home or wherever you are residing to do the following final assessments, which should take about an hour:

- A review of your swallowing
- A questionnaire about how you feel about your swallowing difficulties
- The researchers will ask you about your health since your stroke

Here is a timeline of events:



What happens after the therapy period?

If you continue to have swallowing difficulties after the 2 week therapy period you will remain under the care of the speech and language therapy team for as long as they feel is beneficial.

Where will the research take place?

We will come to you to carry out most of the assessments and therapy – whether that is on this ward or another ward. For the videofluoroscopy you will be taken to x-ray. If you have been discharged home and it suits you and your family we can continue the assessments/therapy at home.

What are the possible benefits of taking part?

You will have a thorough examination of your swallowing and will be given the most appropriate recommendations about the safest foods and drinks for you.

What are the possible disadvantages and risks of taking part?

The aim of the study is to improve your swallowing. It is unknown whether by giving intensive therapy involving repeated swallowing of saliva and in some cases drinks or food there may be an increased risk of infection (aspiration pneumonia) or inflammation of the lung (pneumonitis). This will be monitored very closely as part of the study.

If you take part in this study you will have two Videofluoroscopy assessments, or video x-rays. One or both of these may be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your swallowing and provide your speech therapist with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. We are all at risk of developing cancer during our lifetime due to radiation occurring naturally in the background. Taking part in this study will only increase this risk by a small amount - the amount of radiation from the videofluoroscopy is about 9-times less than the amount of radiation we are exposed to from background radiation per year.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far will not be erased and this information may still be used in the project analysis.

If you are no longer able to participate in the therapy we may still want to continue with the assessments and follow up. Your next of kin or a member of your family will be asked their opinion as to whether this is something that you would want.

Expenses and payments

Participants will not be paid to participate in the study.

Involvement of the medical team/GP?

If you agree to participate in this study a copy of your signed consent form will be filed in your medical records therefore your hospital medical team will be aware that you have agreed to participate in this study. We will also inform your GP.

What if something goes wrong?

In case you have a complaint on your treatment by a member of staff or anything to do with the study, you can initially approach the lead investigator. If this achieves no satisfactory outcome, you should then contact the Hospital Complaints Department, Tel 01332 785156.

Will my taking part in this study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Dr Tim England) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for 1 year after the end of the study so that we are able to contact you about the findings of the study *and* possible follow-up studies. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of

securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

We are also asking for your consent to store and use your videofluoroscopy in possible future research. The videofluoroscopy images and the information gathered about you will be stored by the University of Nottingham at the Royal Derby Hospital, for possible use in future studies. Any samples or data used will be anonymised, and you will not be identified in any way.

What will happen to the results of the research study?

The results will form part of a PhD thesis and it is likely that the research will be written up for submission to a journal. There will be no identifying information about any participants in any publications. The results will be shared with other stroke professionals with the hope that it will contribute to the wider understanding about therapy for people with swallowing difficulties after stroke.

Who is organising and funding the research?

The research is being funded by the NIHR Collaboration for Leadership in Applied Health Research and Care East Midlands (CLAHRC EM).

The research is sponsored by the University of Nottingham.

Who has reviewed the study?

This study has been reviewed and approved by the South Central – Oxford C NHS Research Ethics Committee.

Contact for Further Information

If you require any further information regarding this study please contact:

- Jacqui Benfield, Speech and Language Therapist/Postgraduate Researcher
  Tel: 01332 785891. Email: jacqueline.benfield@nottingham.ac.uk
  Or ask the nurses on the ward to contact the researcher Jacqui Benfield on your behalf

Thank you for your time.

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

NHS National Institute for Health Research

University of Nottingham
School of Medicine
Queen's Medical Centre
Nottingham
NG7 2UH

Derby Teaching Hospitals NHS
NHS Foundation Trust

Patient Information Sheet – Final Version 1.1, 12 June 2017

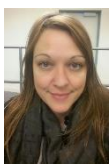
Investigation into whether feedback during swallowing therapy helps patients improve their swallowing in the early stages after stroke.

Research – Swallowing – Eating and drinking

Can you help? Here is some information …..

Where? Here – Royal Derby Hospital

Who?



Jacqui Benfield – Speech and Language Therapist

How long? 2 weeks

Monday

Tuesday

Wednesday

Thursday

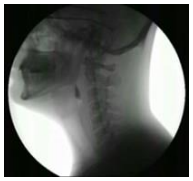
Friday

Visit at home  **n 3 months**

What does it involve?

ASSESSMENT

Videofluoroscopy



Health information

Questionnaire

Bedside swallow assessment

USUAL CARE – Different types

Swallow assessments and reviews

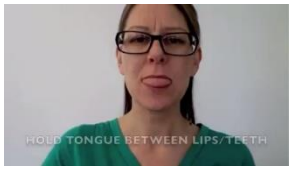
Swallow trials/modified diets

GROUP 1

Therapy with feedback

GROUP 1 & GROUP 2

USUAL CARE EXERCISES



Why have you been chosen?

You have problems swallowing …

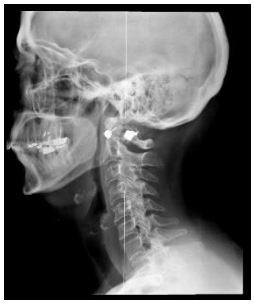
Which group will I be in?

GROUP 1 OR GROUP 2

Benefits?

Can help to improve swallowing…

Any Risks?



Low risk from … Xray

You can choose ….

You can stop at any time.

What if something goes wrong?

If you are unhappy **Tell me!**

If you are still unhappy 

CONTACT:

Hospital Complaints Department, Tel 01332 785156

Will my taking part in this study be kept confidential?

What will happen to the results of the research study?

Publish results

Send you a summary

Present at conferences

Who is organising and funding the research?

NHS
National Institute for Health Research

Collaboration for Leadership in Applied Health Research and Care East Midlands

Who has reviewed the study?

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Oxford C Research Ethics Committee

Contact for Further Information

If you require any further information regarding this study please contact:

Jacqui Benfield,

Speech and Language Therapist

Postgraduate Researcher

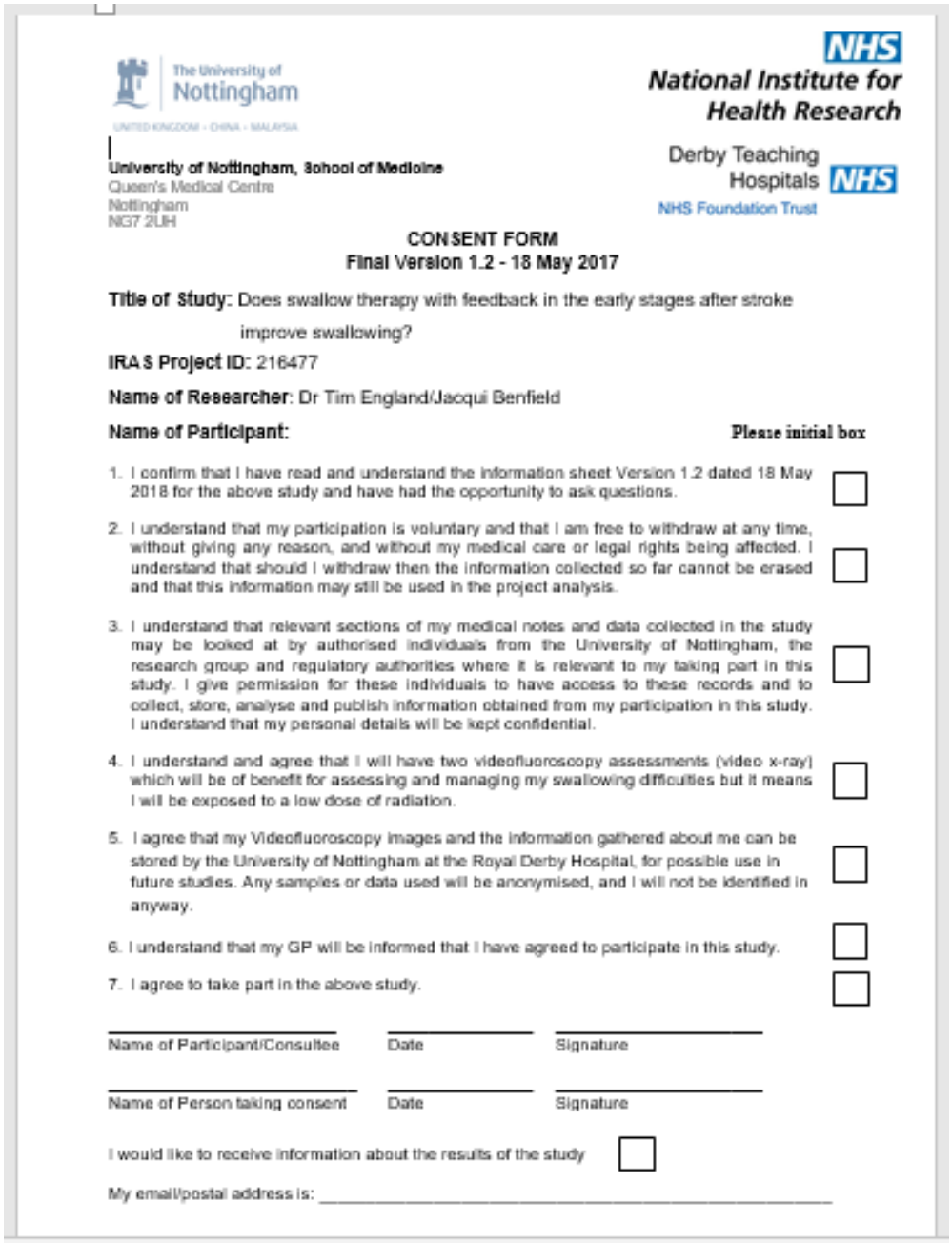
Tel: 01332 785891.

jacqueline.benfield@nottingham.ac.uk

Or ask the nurses on the ward to contact the researcher Jacqui Benfield on your behalf

Thank you for your time

Appendix 18 Consent form - **Feasibility RCT of swallow therapy with biofeedback**



The University of Nottingham
UNITED KINGDOM • CHINA • MALAYSIA

NHS
National Institute for Health Research

Derby Teaching Hospitals NHS
NHS Foundation Trust

University of Nottingham, School of Medicine
Queen's Medical Centre
Nottingham
NG7 2UH

CONSENT FORM
Final Version 1.2 - 18 May 2017

Title of Study: Does swallow therapy with feedback in the early stages after stroke improve swallowing?

IRAS Project ID: 216477

Name of Researcher: Dr Tim England/Jacqui Benfield

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet Version 1.2 dated 18 May 2018 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand and agree that I will have two videofluoroscopy assessments (video x-ray) which will be of benefit for assessing and managing my swallowing difficulties but it means I will be exposed to a low dose of radiation. ☐
5. I agree that my Videofluoroscopy images and the information gathered about me can be stored by the University of Nottingham at the Royal Derby Hospital, for possible use in future studies. Any samples or data used will be anonymised, and I will not be identified in anyway. ☐
6. I understand that my GP will be informed that I have agreed to participate in this study. ☐
7. I agree to take part in the above study. ☐

Name of Participant/Consultee	Date	Signature
Name of Person taking consent	Date	Signature

I would like to receive information about the results of the study ☐

My email/postal address is: _____

Appendix 19 National Institute of Health Stroke Severity Score (NIHSS)

Medscape® www.medscape.com

Category	Score/Description		Date/Time Initials	Date/Time Initials	Date/Time Initials	Date/Time Initials	Date/Time Initials
1a. **Level of Consciousness** (Alert, drowsy, etc.)	0 = Alert 1 = Drowsy 2 = Stuporous 3 = Coma						
1b. **LOC Questions** (Month, age)	0 = Answers both correctly 1 = Answers one correctly 2 = Incorrect						
1c. **LOC Commands** (Open/close eyes, make fist/let go)	0 = Obeys both correctly 1 = Obeys one correctly 2 = Incorrect						
2. **Best Gaze** (Eyes open - patient follows examiner's finger or face)	0 = Normal 1 = Partial gaze palsy 2 = Forced deviation						
3. **Visual Fields** (Introduce visual stimulus/threat to pt's visual field quadrants)	0 = No visual loss 1 = Partial Hemianopia 2 = Complete Hemianopia 3 = Bilateral Hemianopia (Blind)						
4. **Facial Paresis** (Show teeth, raise eyebrows and squeeze eyes shut)	0 = Normal 1 = Minor 2 = Partial 3 = Complete						
5a. **Motor Arm - Left** 5b. **Motor Arm - Right** (Elevate arm to 90° if patient is sitting, 45° if supine)	0 = No drift 1 = Drift 2 = Can't resist gravity 3 = No effort against gravity 4 = No movement X = Untestable (Joint fusion or limb amp)	Left					
		Right					
6a. **Motor Leg - Left** 6b. **Motor Leg - Right** (Elevate leg 30° with patient supine)	0 = No drift 1 = Drift 2 = Can't resist gravity 3 = No effort against gravity 4 = No movement X = Untestable (Joint fusion or limb amp)	Left					
		Right					
7. **Limb Ataxia** (Finger-nose, heel down shin)	0 = No ataxia 1 = Present in one limb 2 = Present in two limbs						
8. **Sensory** (Pin prick to face, arm, trunk, and leg - compare side to side)	0 = Normal 1 = Partial loss 2 = Severe loss						
9. **Best Language** (Name item, describe a picture and read sentences)	0 = No aphasia 1 = Mild to moderate aphasia 2 = Severe aphasia 3 = Mute						
10. **Dysarthria** (Evaluate speech clarity by patient repeating listed words)	0 = Normal articulation 1 = Mild to moderate slurring of words 2 = Near to unintelligable or worse X = Intubated or other physical barrier						
11. **Extinction and Inattention** (Use information from prior testing to identify neglect or double simultaneous stimuli testing)	0 = No neglect 1 = Partial neglect 2 = Complete neglect						
	TOTAL SCORE						

INITIAL	SIGNATURE	INITIAL	SIGNATURE	INITIAL	SIGNATURE

156337 1004

Source: J Neurosci Nurs © 2006 American Association of Neuroscience Nurses

Appendix 20 Biofeedback treatment session protocol

Biofeedback Session protocol

Initial session

- Prior to session create participant profile with trial ID
- Explain the therapy to the participant
- Demonstrate the electrode placement and swallow signal obtained (test.pat)
- Demonstrate the effortful swallow - hit
- Demonstrate the timing swallow – hit
- Enter strength training mode
- Connect the sEMG and allow participant to practice
    - Regular swallows
    - Effortful swallows – prompt to swallow hard/strong and imagine you are swallowing a golf ball.

Session plan

1. Prior to session open participant profile
2. Place triode electrode on submental muscles and fix with tape/bandage
3. Enter strength training mode
4. **Calibrate**
    a. 30 second run with no swallows
    b. Press remove DC offset
    c. Ask participant to perform 1 x swallow per 30 seconds
    d. Repeat 5 times
    e. Mark each swallow.

5. **Strength training**
    a. 1 x trial per 30 seconds to achieve a hit
    b. Block 1 - 10 trials
    c. 100 seconds break – sips/teaspoons/swabs safe fluids
    d. Block 2 - 10 trials
    e. 100 seconds break
    f. Block 3 - 10 trials

6. **Skill training**
    a. Disconnect and exit strength training mode
    b. Save results
    c. Open Skill training session
    d. Block 1 – 10 trials
    e. 100 second break – sips/teaspoons/swabs safe fluids
    f. Block 2 – 10 trials
    g. 100 second break
    h. Block 3 – 10 trials
7. END session – complete CRF

NB: If unable to complete Skill training – continue with strength training and vice versa. If failing completely on 3 blocks despite minimal challenge – STOP session. Repeat for a further 2 sessions and if this continues STOP intervention.

Appendix 21 Modified Rankin Scale

Score	Description
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all usual duties and activities
2	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	Moderate disability; requiring some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	Dead

TOTAL (0–6): _____

Appendix 22 Barthel Index

THE BARTHEL INDEX

Patient Name: _____
Rater Name: _____
Date: _____

Activity	Score
FEEDING 0 = unable 5 = needs help cutting, spreading butter, etc., or requires modified diet 10 = independent	_____
BATHING 0 = dependent 5 = independent (or in shower)	_____
GROOMING 0 = needs to help with personal care 5 = independent face/hair/teeth/shaving (implements provided)	_____
DRESSING 0 = dependent 5 = needs help but can do about half unaided 10 = independent (including buttons, zips, laces, etc.)	_____
BOWELS 0 = incontinent (or needs to be given enemas) 5 = occasional accident 10 = continent	_____
BLADDER 0 = incontinent, or catheterized and unable to manage alone 5 = occasional accident 10 = continent	_____
TOILET USE 0 = dependent 5 = needs some help, but can do something alone 10 = independent (on and off, dressing, wiping)	_____
TRANSFERS (BED TO CHAIR AND BACK) 0 = unable, no sitting balance 5 = major help (one or two people, physical), can sit 10 = minor help (verbal or physical) 15 = independent	_____
MOBILITY (ON LEVEL SURFACES) 0 = immobile or < 50 yards 5 = wheelchair independent, including corners, > 50 yards 10 = walks with help of one person (verbal or physical) > 50 yards 15 = independent (but may use any aid; for example, stick) > 50 yards	_____
STAIRS 0 = unable 5 = needs help (verbal, physical, carrying aid) 10 = independent	_____
TOTAL (0–100):	_____

Appendix 23 The Signs of Depression Scale (SDSS)

3.1 The Signs of Depression Scale (SDSS)

Original reference	Hammond MF, O'Keeffe ST, Barer DH. Development and validation of a brief observer-rated screening scale for depression in elderly medical patients. *Age and Ageing* 2000;**29**(6):511–5
Copyright	British Geriatrics Society. The scale is freely available with permission from the authors
Contact details	Margaret F Hammond, Department of Primary Care, University of Liverpool Whelan Building, The Quadrangle, Brownlow Hill, Liverpool L69 3GB Fax: +44 (0) 151 794 5604 Email: mhammond@liverpool.ac.uk

Signs of Depression Scale (SDSS)

1. Does the patient sometimes look sad, miserable or depressed?	Yes / No
2. Does the patient ever cry or seem weepy?	Yes / No
3. Does the patient seem agitated, restless or anxious?	Yes / No
4. Is the patient lethargic or reluctant to mobilise?	Yes / No
5. Does the patient need a lot of encouragement to do things for him/herself?	Yes / No
6. Does the patient seem withdrawn, showing little interest in the surroundings?	Yes / No
(Score 1 for 'Yes' and 0 for 'No') **Total Score**	

Appendix 24 Dysphagia Handicap Index (DHI)

Please place a check in the box that describes your swallowing difficulty.

	Never	Sometimes	Always
1P. I cough when I drink liquids.			
2P. I cough when I eat solid food.			
3P. My mouth is dry.			
4P. I need to drink fluids to wash food down.			
5P. I've lost weight because of my swallowing problem.			
1F. I avoid some foods because of my swallowing problem.			
2F. I have changed the way I swallow to make it easier to eat.			
1E. I'm embarrassed to eat in public.			
3F. It takes me longer to eat a meal than it used to.			
4F. I eat smaller meals more often due to my swallowing problem.			
6P. I have to swallow again before food will go down.			
2E. I feel depressed because I can't eat what I want.			
3E. I don't enjoy eating as much as I used to.			
5F. I don't socialize as much due to my swallowing problem.			
6F. I avoid eating because of my swallowing problem.			
7F. I eat less because of my swallowing problem.			
4E. I am nervous because of my swallowing problem.			
5E. I feel handicapped because of my swallowing problem.			
6E. I get angry at myself because of my swallowing problem.			
7P. I choke when I take my medication.			
7E. I'm afraid that I'll choke and stop breathing because of my swallowing problem.			
8F. I must eat another way (e.g., feeding tube) because of my swallowing problem.			
9F. I've changed my diet due to my swallowing problem.			
8P. I feel a strangling sensation when I swallow.			
9P. I cough up food after I swallow.			

Please circle the number that matches the severity of your swallowing difficulty (1 = no difficulty at all; 4 = somewhat of a problem; 7 = the worse problem you could have)						
1	2	3	4	5	6	7
Normal			Moderate			Severe

Appendix 25 Description of videofluoroscopy measures

Timing measures	Description	Frame calculation
Global oral transit time (gOTT, seconds)	The interval between the frame showing onset of any 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	TF2-TF1
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	TF3-TF2
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	TF5-TF3
Laryngeal closure duration (LCD, seconds)	The interval from the frame showing contact of the arytenoids with base of the epiglottis (airway closure) to the last frame showing this contact has discontinued (airway opening)	TF8-TF5
Maximum hyoid displacement duration (MHD, seconds)	The interval from the first frame showing maximum superior hyoid elevation and the frame when the hyoid begins to descend	TF7-TF6
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)	TF10-TF4
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	TF10-TF2
Upper oesophageal sphincter duration (UOSD, seconds)	The interval from first opening of the UOS (as signified by a column of air at the top of the narrowest past of the UOS or of contrast entering the narrowest part of the UOS) to the frame showing the tail of the bolus passing into the UOS	TF10-TF9
Displacement measures		
Anterior hyoid displacement (AHD, mm)	Maximum anterior position the hyoid achieves in comparison to the C2C4 plane	HA-Max-HA-Rest
Superior hyoid displacement (SHD, mm)	Maximum superior position the hyoid achieves in comparison to the C2C4 plane	HS-Max-HS-Rest
Ratings		
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	
Pharyngeal residue (PR, range 0-4)	Residue in pharynx. 0: complete pharyngeal clearance; 1: trace residue within or on pharyngeal structures; 2: collection of residue within or on pharyngeal structures; 3: majority of contrast within or on pharyngeal structures; 4: minimal to no pharyngeal clearance.	

Appendix 26 Methodology for measuring anterior and superior hyoid displacement

Step 1

Find the key hyoid position frames:

a. Track the hyoid from frame prior to active tongue movement until it returns to rest post swallow.
b. On kinovea – right click – track path. Set to finest pen size and move the cross to the anterior inferior part of the hyoid. It will track the movements – but you need to check that the cross remains in position and adjust as necessary.
c. Play back with grid (add from menu) and choose the required frames.

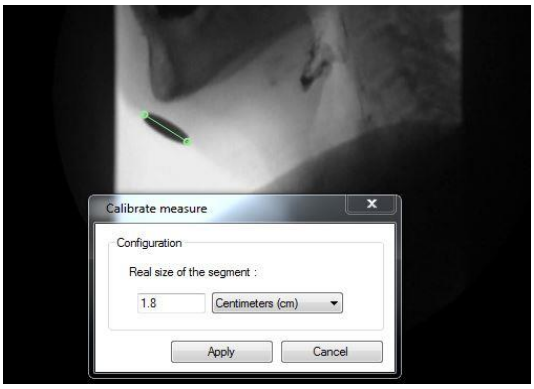
2. Choose the resting hyoid frame – record the frame number
    a. Choose the frame before the frame where bolus transfer initiates. Note that the fully resting position of the hyoid i.e. post swallow or prior to bolus entering the mouth will be even lower but this is not the frame we want.
3. Choose the maximum superior frame – record the frame number
4. Choose the maximum anterior frame – record the frame number

Step 2

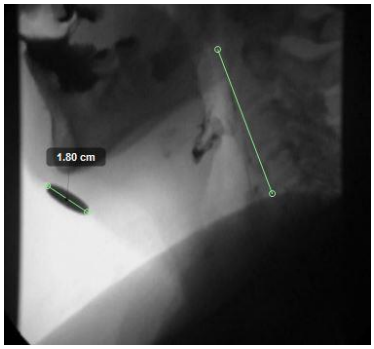
Measure the hyoid position from the C2/C4 plane or perpendicular

You will have the frame numbers of each of the Resting, Sup Max and Ant Max hyoid

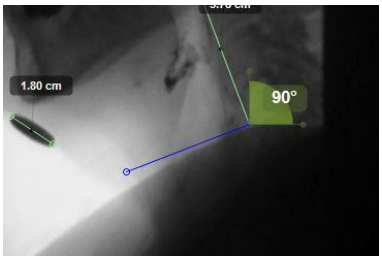
1. Calibrate the measurement by drawing a line across the marker under the chin. Right click on the line and choose calibrate. Enter 1.8 and cm.

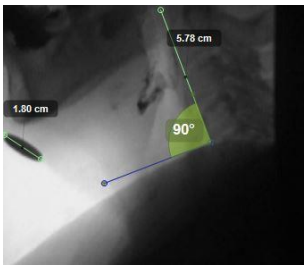


2. Draw a C2-C4 plane. Choose the anterior inferior corner of the C4 and draw up passed the anterior inferior corner of C2 up passed the mandible.

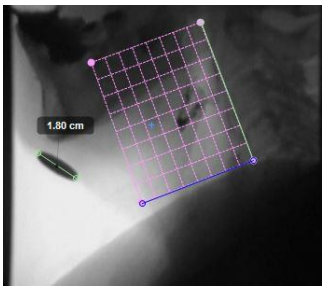


3. Make a perpendicular line at C4 by adding an angle at C4. Right click and invert the angle. Then adjust it so the vertical line is at the same angle as the C2-C4 plane. And the angle is 90 degrees. Then draw a line along the perpendicular and delete the angle (right click).

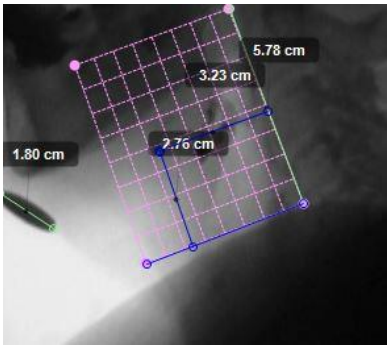




4. Mark the anterior inferior location of the hyoid with a cross marker
5. Add a perspective grid and fit it to the space



6. Draw a line from the hyoid to the perpendicular line (S) (don't need when doing Ant Max)
7. Draw a line from the hyoid to the C2-C4 plane (A) (don't need when doing Sup Max)
8. Right click both lines and select display measure



9. Record the measures for S and A as required.

NB: All the tools mentioned are on the tool bar at the bottom. To adjust lines you need to go out of the line option back to the hand icon (move). To make lines smaller – right click and choose size and colour and choose the thinnest line possible.