

# IQoro Dysphagia Therapy in an NHS setting: A Service Evaluation

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## Abstract

**Background:** Swallowing is a complex process and difficulties with this (dysphagia) can have significant physical and psychological consequences and present a substantial cost to health care services. IQoro is a neuromuscular therapy option which aims to improve dysphagia. This evaluation explored the introduction of IQoro into a National Health Service (NHS) setting.

**Method:** Patients with chronic dysphagia were recruited from acute and community settings and completed a 12-week programme using IQoro. Clinical and well-being measures were taken pre- and post-training. Feedback was gained from the SLTs delivering this programme.

**Results:** 25 patients were recruited into the evaluation. There were significant improvements in self-reported quality of life (QoL) scores, including the burden of dysphagia and mental health. There was significant improvement in functional measures of dysphagia, including the consistencies of food and drink that patients' could safely manage. Feedback from SLTs indicated that IQoro improved the range of therapy options and that they would likely use it again.

**Conclusion:** IQoro can be successfully introduced into an NHS team and can be effective in supporting patients with chronic dysphagia. However, factors such as the ability to follow patients across different settings and the individual risk of further decline need to be considered.

### Key Words

Dysphagia, IQoro, Therapy, Swallowing, Intervention

## Introduction

Swallowing is a complex process, which requires many movements to happen at in a highly coordinated and rapid fashion due to the initial shared route for air and food and the apnoea that occurs during this process (Leslie, Carding and Wilson, 2003; Dziewas et al, 2017). Impairments to this process (dysphagia) are associated with a variety of conditions, including stroke, respiratory conditions such as COPD, illnesses and surgery (Roy et al, 2007; Bath, Lees and Everton, 2018).

Data from the US and Australia suggests that the prevalence of swallowing disorders is between 16-37.6% of the adult population (Roy et al, 2007; Eslick and Talley, 2008). Dysphagia is associated with many physical and psychological consequences. When not appropriately managed it puts people at an increased risk of dehydration, malnutrition, respiratory infections, pneumonia and death (Ekberg et al, 2002; Hong and Yoo, 2017). Adults with dysphagia also report significantly higher levels of depression and anxiety compared to the non-dysphagic population (Eslick and Talley, 2008; Youssof et al, 2017). Ekberg et al (2002) found that 40% of people with dysphagia reported anxiety or panic during mealtimes, 35% avoided eating with other people and up to 60% reported loss of enjoyment of mealtimes. Reduced quality of life (QoL) has also been identified (Youseff et al, 2017; Eslick and Talley, 2008). Hong and Yoo (2017) demonstrated that the impact of dysphagia on QoL was affected by the severity, with significantly lower QoL scores among people unable to have any oral intake, compared to people having some or adapted oral intake. The physical, psychological and financial consequences from dysphagia can continue in the long-term. Smithard et al (1997) found that 15% of people diagnosed with dysphagia post-stroke continued to have difficulties and were unable to return to their pre-stroke diets 1 month later. 1-13% of people with dysphagia are estimated to continue to have unsafe swallows at 6 months post-onset (Mann, Hankey and Cameron, 1999; Smithard et al, 1997).

There is a measurable cost to dysphagia. Department of Health figures found that 23,000 people received a primary diagnosis of dysphagia in England and Wales in 2001-2, resulting in 76,000 days in hospital (Leslie, Carding and Wilson, 2003), a significant cost to both the patient and health service. In a systematic review, Attrill et al (2018) identified that patients with oro-pharyngeal dysphagia had a significantly longer length of stay in hospital compared with patients without oro-pharyngeal dysphagia. Not all studies included in this review considered the cost of hospital stay, but those that did demonstrated an average cost 40.36% higher for patients with dysphagia.

The clear physical, psychological and financial consequences of dysphagia, highlights the importance of identifying effective treatments, which can reduce the impact and shorten the duration of dysphagia. One treatment option currently receiving attention is the IQoro neuromuscular training device. The IQoro training is designed to stimulate sensory receptors in the intra-oral mucosa and causes increased tone in the lips and the muscles of the base of the mouth, this then triggers the tongue to retract and increase tone in the stylohyoid muscles and the digastric muscles. The retraction of the tongue also provides sensory stimulation to the faucial arches and the soft palate (Hägg and Tibbling, 2013). This sequence of activity in the muscles is also known as the buccinator mechanism and has been previously identified as being triggered during the swallow process (Perkins, Blanton and Briggs, 1977). The importance of lip strength in the swallow process has also been separately identified (Hägg and Anniko, 2010).

There is a growing interest in IQoro therapy in the UK. The National Institute of Clinical Excellence (NICE) has released a Medtech briefing (MB175) identifying IQoro as a potential treatment for dysphagia, but also highlighting the need for further research and the need to understand whether this therapy can be effectively used within the National Health Service (NHS). Much of the early

research into the IQoro therapy was limited by small sample sizes and often used pre-post analyses rather than including control groups (Hägg and Anniko, 2008; Hägg and Tibbling, 2015). However, a recent cluster randomised control trial (Hägglund et al, 2019) supports early conclusions about the effectiveness of this therapy and suggests that it could be used with adults with dysphagia resulting from a range of conditions.

This service evaluation will focus on the following research questions:

- Can IQoro dysphagia therapy be used to support patients who have shown limited improvement with standard care?
- Does IQoro therapy result in functional changes to what people with dysphagia can eat and drink?
- Does IQoro therapy result in changes to people's self-reported quality of life related to their eating and drinking?
- Can IQoro therapy be used within an NHS SLT service?

## Method

### Participants

Participants were recruited from both the acute and community caseloads supported by the Speech and Language Therapy team at the Royal Devon and Exeter NHS Foundation Trust (RD&E), between May 2019 and December 2019. The inclusion criteria were people (1) diagnosed with oropharyngeal dysphagia by a Speech and Language Therapist (SLT); (2) with dysphagia continuing for at least 10 days after onset; (3) with dysphagia that was not improving or was improving more slowly than expected (clinical judgement); (4) able to follow the instructions for the therapy; (5) able to understand the information about the therapy and the service evaluation enough to give informed consent.

### Procedure

Potential participants were identified during routine dysphagia assessments, they were initially informed about the study by the SLTs completing these assessments. Once a potential participant was identified who met the inclusion criteria a feasibility assessment was completed, this involved trialling an IQoro device to consider whether they could tolerate the pre-dental placement required for the therapy, whether they could understand the instructions and tolerate the therapy exercise, what level of support would be needed (i.e. could they train independently or would family or carers be needed to assist with the therapy) and the size of device that they could use (large or small). During this initial assessment participants also signed the consent form to participate in the evaluation.

### IQoro

The training involved inserting the IQoro device pre-dentally and pulling forwards against resistance from the lips, this was completed 3 times for 5-10 seconds each time. Participants were requested to complete this training 3 times a day for 12 weeks. This training was demonstrated with participants during an introductory session, training was then completed by the participant themselves, or with support from SLTs, family or carers depending on the participant's location (hospital or community) and their level of support need.

Before the start of the service evaluation all SLTs involved received a training session covering the IQoro training method, how it affects the swallow and the baseline and outcome measures that were used. A total of 16 SLTs were involved in supporting participants with the training and these

SLTs were based in a range of settings including acute hospitals (n=4), community (n=9) and rehabilitation units (n=3).

## Measures

Demographic characteristics of the patients were collected at the start of therapy. This included age, gender, onset of dysphagia and medical diagnosis. A series of clinical and well-being measures were also taken pre- and post-treatment for comparison. These were:

- International Dysphagia Diet Standardisation Initiative Functional Diet Scale (IDDSI-FDS) levels (Cichero et al, 2017) were used to consider functional changes in the ability of each participant to eat and drink. These levels were assessed by an SLT during clinical assessment or videofluoroscopy assessment depending on individual need of the patient. IDDSI provides a consistent and structured approach to describing both diet and fluid consistencies which can be recommended for people with dysphagia. It covers fluid levels starting at normal fluids and covering progressively thicker fluids (levels 0-4), and diet textures from pureed diet, through to normal diet (levels 4-7). In the analysis additional levels were included to allow for consideration of participants who were nil by mouth for fluids or diet or who were only having oral trials (very small, controlled amounts of food or fluids).
- Therapy Outcome Measures (TOMS) Dysphagia (Enderby and John, 2006) utilises the World Health Organisation International Classification of Functioning, Disability and Health (WHO-ICF) (WHO, 2002) to provide outcome ratings for rehabilitation across the domains of impairment, activity, participation and well-being. The TOM scales have been shown to have good reliability and validity (Enderby, John and Petheram, 2006). Each of the four subscales are scored from 0-5, progressing from profound difficulty at 0 to normal presentation at 5.
- The Functional Impairment Measure and Functional Assessment Measure (FIM/FAM) Swallowing (Turner-Stokes et al, 1999) is designed as a measure of disability, it is rated across seven levels, from unable to have any food or drink orally (level 1) to maintaining a fully normal diet and fluids without assistance or the use of strategies (level 7). It has demonstrated high inter-rater reliability (Turner-Stokes et al, 1999).
- The Facial Activity Test (Hägg and Larsson, 2004; Hägg and Tibbling, 2015) was designed to measure facial movement and symmetry in adults' post-stroke. Scores calculated into Upper Right, Upper Left, Lower Face. Scoring is on a 0-4 scale (normal function-no function). Inter- and intra-rater reliability for this assessment were confirmed by Hägg and Larsson (2004).
- The Drooling Severity Test (DST; Thomas-Stonell and Greenberg, 1988) is a simple scale, which separately considers the frequency of drooling and the severity. Scoring is based on clinician judgement. This scale has been used with a range of populations including adults with drooling induced by antipsychotic medication (Blissit Touma, Tillery and Pacheco, 2014) and children with cerebral palsy (Senner et al, 2004).
- The Swallowing Quality of Life Questionnaire (SWAL-QOL) contains 44-items, divided into 10 domains (30-items) and a 14-item Dysphagia Symptom Battery, DSB (McHorney et al., 2000a; McHorney et al., 2000b; McHorney et al., 2002). The 10 domains of the SWAL-QOL are: burden, eating duration, eating desire, food selection, fear, mental health, social functioning, communication, sleep, and fatigue. Each item is given a score from 0 to 4 (worst-best). Scoring in each domain and the DSB is calculated by the sums of scores for each item expressed as a percentage of the maximum possible domain score. A composite score was derived using the method of Plowman-Prince et al. (2009) where the average score of the 10 domains (not including the DSB) was calculated. For patients who were nil by

mouth, only items in each domain that were applicable were used to calculate domain scores.

- A record was also kept at the start and end of the therapy of patients who were nil by mouth (NBM) and fed non-orally, either by percutaneous endoscopic gastrostomy (PEG) or nasogastric tube (NGT).

Following the recruitment and data collection with the patients, the SLTs who had been involved in supporting patients with the IQoro therapy were sent a 22-item online survey to explore their experiences of this service evaluation and their beliefs and confidence in using the IQoro. This survey included yes/no, multiple choice, 5-point Likert scales and open text responses. This survey was created using an iterative process between the first and last authors. It was designed and sent to the SLTs using Survey Monkey (SurveyMonkey Inc). A copy of this survey is available on request from the last author.

### Analysis

All statistical analyses were performed using IBM SPSS Statistics 26. Patients that were missing either baseline or post-intervention scores were excluded from the analysis of each test. Wilcoxon's signed rank tests were used to analyse changes in patients test scores between baseline and post-intervention. A *P* value of <0.05 was regarded as statistically significant.

The results of the SLT survey were analysed through frequency counts of the quantitative questions using the analysis software within Survey Monkey. Responses to open text questions were analysed using frequency counts and content analysis (Hsieh and Shannon, 2005), using a table created in Microsoft Excel (Microsoft Corporation, 2018), the first author grouped the responses by the ideas presented in them, then identified overarching categories. The categories were reviewed by the last author.

### Ethical Approval

Ethical approval for this service evaluation was given by the clinical governance panel of the RD&E.

## Results

### Recruitment

The recruitment process is shown in Figure 1. A total of 25 people were recruited for the evaluation. Demographic details are shown in Table 1. A majority were male, stroke patients, with an average age of 70 years and had been living with dysphagia for on average 9 months.

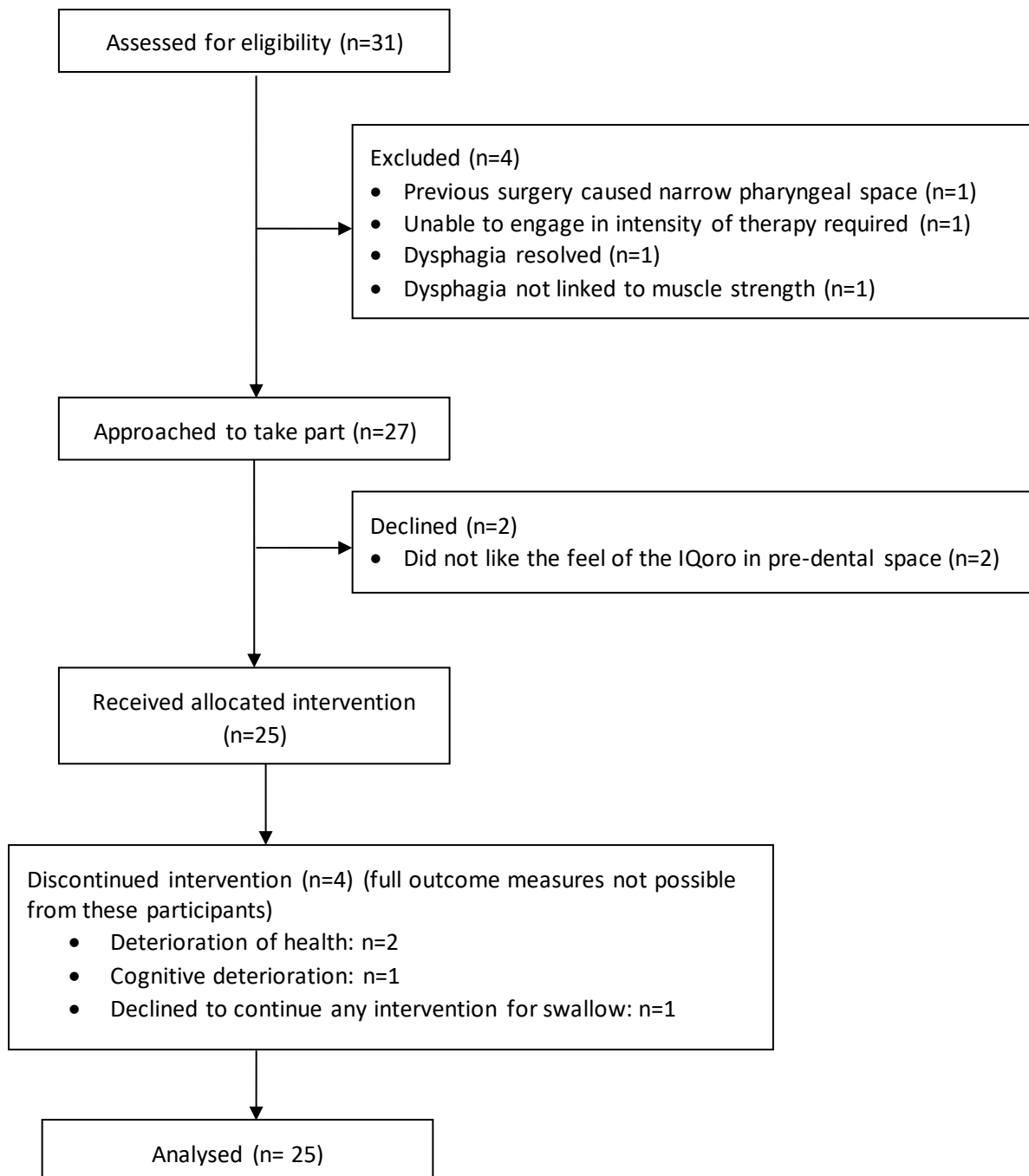


Figure 1. Flow of participants through the evaluation

Table 1. Participant demographic characteristics

		n (%)
<b>Gender</b>	Male	13 (52%)
	Female	12 (48%)
<b>Age</b>	Range	33-95 years
	Mean (SD)	70.16 years (16.3)
<b>Diagnosis</b>	Stroke (incl. infarct and haemorrhage)	19 (76%)
	Critical illness myopathy or poly neuropathy	4 (16%)
	Other (incl. familial amyloid polyneuropathy, mitochondrial disease)	2 (8%)
<b>Duration of dysphagia</b>	Range	10 days – 26 months
	Mean (SD) in months	8.81 (11.03)

SD – standard deviation

#### Impact of iQoro

Table 2 presents the summary data for the DSB and the 10 domains of the SWAL-QOL for patients before and after the programme. There were statistically significant improvements in the SWAL-QOL composite score ( $p=0.04$ ) and DSB ( $p=0.03$ ), as well as improvements in the food selection ( $p=0.01$ ), burden ( $p<0.01$ ), and mental health ( $p=0.01$ ) sub-domains of the SWAL-QOL. Changes from pre- to post-training indicated a significant reduction in the impact dysphagia had on quality of life ( $p=0.01$ ) with 52.4% of patients categorised as mild/no impact after receiving iQoro.

Table 2. Change overtime in the SWAL-QoL composite and subdomains, median (IQR)

	Baseline	Post training	<i>p</i>
	Median (IQR)	Median (IQR)	
<b>DSB (n=19)</b>	62.5 (33.9)	67.9 (21.7)	0.03*
<b>SWAL-QOL Composite Score (n=20)</b>	60.8 (31.2)	72.7 (18.1)	0.04*
Food selection (n=15)	50.0 (75.0)	87.5 (37.5)	0.01*
Burden (n=20)	37.5 (56.3)	75.0 (50.0)	<0.01*
Mental health (n=20)	57.5 (53.8)	80.0 (33.1)	0.01*
Social functioning (n=18)	52.5 (47.5)	72.5 (70.0)	0.21
Fear (n=18)	75.0 (35.9)	66.7 (11.5)	0.15
Eating duration (n=14)	25.0 (59.4)	56.3 (43.8)	0.09
Eating desire (n=19)	58.3 (50.0)	75.0 (41.7)	0.09
Communication (n=20)	68.8 (71.9)	75.0 (50.0)	0.39
Sleep (n=20)	100.0 (50.0)	87.5 (46.9)	0.93
Fatigue (n=20)	50.0 (39.6)	66.7 (25.0)	0.09
	<b>Percentage</b>	<b>Percentage</b>	
<b>Impact of Dysphagia</b>			0.01*
Severe Impact (0-49)	33.3%	14.3%	
Moderate Impact (50-70)	37.5%	33.3%	
Mild/No Impact (71-100)	29.2%	52.4%	

\* Significant difference from before and end of programme ( $p<0.05$ )

SWAL-QOL = Swallowing quality of life, IQR = Interquartile range, DSB = Dysphagia symptom battery



Table 3 shows statistically significant improvements in patients' FAM, IDDSI-FDS and TOMS scores from baseline to post-intervention ( $p < 0.05$ ). For the IDDSI-FDS, there were statistically significant improvements in drink ( $p = 0.01$ ) and food ( $p = 0.01$ ) scores. Along with statistically significant improvements in all of the TOM subscales: impairment ( $p = 0.01$ ), activity ( $p < 0.01$ ), participation ( $p < 0.01$ ), and well-being ( $p < 0.01$ ) and lower face FAT scores ( $p = 0.01$ ).

Table 3. Change in functional measures, median (IQR)

	Baseline	Post training	<i>p</i>
<b> Drooling</b>			
Drooling Severity (n=22)	1.00 (2.00)	1.00 (2.00)	0.56
Drooling Frequency (n=22)	1.00 (2.00)	1.00 (1.25)	0.08
<b>FAM (n=23)</b>	4.00 (4.00)	6.00 (1.00)	<0.01*
<b>FAT</b>			
Upper Left (n=20)	0.00 (0.30)	0.00 (0.22)	0.15
Upper Right (n=20)	0.00 (0.00)	0.00 (0.00)	0.29
Lower Face (Left & Right) (n=19)	0.90 (1.65)	0.50 (0.93)	0.01*
<b>IDDSI-FDS</b>			
Foods (n=22)	5.00 (5.00)	7.00 (1.75)	0.01*
Drinks (n=22)	2.50 (6.00)	0.00 (2.75)	0.01*
<b>TOM (n=16)</b>			
Impairment (n=23)	2.00 (2.50)	3.50 (1.50)	0.01*
Activity (n=23)	3.00 (3.50)	4.00 (2.50)	<0.01*
Participation (n=23)	4.00 (1.00)	4.00 (1.00)	<0.01*
Well-being (n=23)	3.50 (1.00)	4.00 (1.00)	<0.01*

\* Significant difference between before and end of programme ( $p < 0.05$ )

IQR = Interquartile range, FAM = Functional assessment measure, FAT = Facial activity test, IDDSI-FDS = International dysphagia diet standardisation initiative functional diet scale, TOM = Therapy outcome measure

	Baseline	Post-training
Enteral feeding (including PEG and NGT)	10	6

## Feedback from SLTs

Of the 16 SLTs supporting patients, 13 (81%) responded to the electronic survey.

The SLTs had supported an average of 2 patients (due to the shared caseloads multiple SLTs may have been involved in supporting the same patients). All SLTs reported that they understood the aims of using the IQoro training (strongly agree 46.15%, N=6, agree 53.85%, N=7). They were more split regarding whether the IQoro training led to positive outcomes (strongly agree 23.08%, N=3, Agree 30.77%, N=4, unsure 30.77%, N=4, disagree 0, Strongly disagree 7.69%, N=1). However, there was general agreement that IQoro therapy improves the therapy options that can be offered to patients (strongly agree 61.54%, N=8, agree 23.08%, N=3, unsure 7.69%, N=1, disagree/strongly disagree N=0). Most SLTs reported that they would use IQoro therapy again, with other patients in their caseload (strongly agree 46.15%, N=6, agree 46.15%, N=6, unsure 7.69%, N=1). Many also reported that they would recommend IQoro therapy to other SLTs (strongly agree 46.15%, N=6, agree 38.46%, N=5, unsure 15.38%, N=2).

SLTs were asked whether their experience with the IQoro therapy changed their clinical practice or thinking around dysphagia and dysphagia therapy. There were eleven therapists who provided responses to this question. Many therapists reflected on IQoro, while considering their other therapy options (N=9). From this group, there were 2 strong sub-narratives, one that IQoro simply offered another tool that could be used (N=4). The other group (N=5) reflected on the difference in their own thinking, this included considering intervention versus compensation in the treatment of dysphagia and how to increase patient compliance by focusing on a therapy programme that is "quick and easy to use" (SLT based in [location]). There was also consideration of the patients that IQoro could be used with (N=4), this included patients who were unable to start oral trials (N=2) (small amounts of food or drink introduced in a controlled way to practice swallowing while minimising risk), neurological patients (N=1), particularly stroke patients and those who are not progressing using other therapies (N=1).

## Discussion

This evaluation focused on the IQoro dysphagia therapy device and its use with an adult population within an NHS Trust.

Participants were recruited for this evaluation if they presented with chronic dysphagia (dysphagia persisting for at least 10 days), with an average duration of 9 months. From the 25 participants originally enrolled on the evaluation, 21 completed 12 weeks of training. Of these 4 participants who stopped the training early, only one was due to disengaging with the therapy, the other three experienced deteriorations in their physical or cognitive status, making further therapy inappropriate. This demonstrated that IQoro can be used with people who are experiencing chronic dysphagia. Additionally, participants demonstrated positive benefits from the therapy. The TOM scores show significant changes across all 4 domains, meaning that participants experienced decreased impairment, improved activity, ability to participate in their daily lives and improved well-being. Participants also reported significantly fewer dysphagia related symptoms on the DSB, further suggesting that there were improvements to their swallow despite the prolonged duration of their dysphagia prior to starting this therapy.

Previous studies into the IQoro therapy have focused on measures of swallow efficiency such as the timed water swallow test (TWST) (e.g. Hägglund et al, 2019; Hägg and Tibbling, 2013). While this provides the ability to compare to normative data it does not match typical eating and drinking, nor does it demonstrate whether people experience a meaningful change in their day-to-day function following the therapy. This evaluation instead considered whether there was a change to the consistencies of food and drink that people were able to safely manage. This evaluation found that there were clear changes to the consistencies of food and drink that people were able to manage before and after using IQoro. This was shown through the FAM and the IDDSI recommendations that participants were on. The FAM score indicates that on average participants moved from modified diet and fluids to normal diet and fluids with compensatory strategies. The IDDSI levels gave detail on the amount of change, participants typically moved from a minced and moist diet (IDDSI level 5) and level 2 thickened drinks to normal diet (IDDSI level 7) and drinks (IDDSI level 0). There were also four participants who showed an even greater change, as they moved from enteral feeding for all intake to fully oral intake for both diet and fluids. All four ended the training having normal diets and either normal fluids or level 1 thickened fluids. These changes demonstrate that the improved function following the IQoro training and a meaningful change in peoples' day-to-day lives.

In this evaluation the Swal-Qol (McHorney et al, 2000a, b) was used to consider self-reported QoL related to eating and drinking. The well-being subtest of the TOMs score suggests that participants' overall well-being showed significant improvement. This was supported by participants' own self-reported scores on the Swal-Qol, their overall QoL score showed significant improvement. However, the Swal-Qol subtests were more varied. Scores linked to ease of selecting food, the perceived burden of dealing with the dysphagia and overall mental health show significant improvements. However, there was no significant change in anxiety or fear in relation to eating and drinking. This suggests that participants' may still be experiencing anxiety about their swallow or eating and drinking, but other aspects of their mental health may have improved. Previous research has highlighted the importance of the psychological consequences of dysphagia (Elick and Talley, 2008; Youseff et al, 2017; Ekberg et al, 2002). Therefore, treatments that also impact this area are valuable to consider. The lack of change in reported anxiety scores may benefit from further exploration in future studies. Previous research into IQoro therapy has reported overall changes to QoL and perception of dysphagia (e.g. Hägglund et al, 2019; Hägg and Tibbling, 2013), but has not broken this down into finer areas, such as burden of dysphagia or feelings of depression or anxiety. The lack of significant change in reported social participation may have been impacted by recruitment of participants from the acute hospital. This group are less likely to be able to experience changes in eating out or socialising connected with food and drink. Eating duration also showed no significant change, this may be linked to the continued use of strategies when eating and drinking (as shown by the FAM scores), which can increase the time taken.

As part of this service evaluation IQoro therapy was introduced to an SLT team working within an NHS Trust. There were 25 participants enrolled on the evaluation and 21 (84%) successfully completed the full 12 weeks of training. The ability to follow people from the acute hospital to the community—allowed continuity of support as SLTs in the acute and community settings were both trained in IQoro therapy. This may be an important consideration for teams considering the introduction of IQoro. The 4 people who stopped training early did so due to individual reasons, not due to staff difficulties implementing or supporting the training.

The SLTs involved in the evaluation provided positive feedback about use of the IQoro therapy. 92% would use it again and 85% would recommend it to other SLTs. This further supports the conclusion that IQoro therapy is not only possible within an NHS Trust, but can be a positive experience for SLTs and patients alike. Training for the SLTs was an important part of this success, this would be an important consideration when introducing this therapy.

This evaluation used a before-after analysis to consider the impact of IQoro therapy. People with chronic dysphagia were recruited in an attempt to reduce the impact of spontaneous recovery on the results. However, this type of analysis reduces control over variables and so limits the ability to draw firm conclusions about the effectiveness of the intervention.

This study did not include any consideration of the cost of treating dysphagia. Previous studies have demonstrated increased length of hospital stay and increased cost for patients with dysphagia (Atrill et al, 2018). Future studies could consider whether introduction of IQoro therapy into dysphagia management could reduce hospital stays and the impact on cost of patient treatment for the health care provider.

This evaluation did not include an objective measure of dysphagia such as videofluoroscopy. While this evaluation used dysphagia assessments by trained professionals, there are questions over the reliability of clinical swallow assessments both between different SLTs and across time (McCullough

et al, 2000). Future studies could also include videofluoroscopy or Fiberoptic Endoscopic Evaluations (FFEs) to objectively assess for changes in the swallow.

### Conclusions

This service evaluation has demonstrated that IQoro therapy can be successfully introduced to a SLT service within an NHS Trust. It also demonstrated that IQoro therapy can have a significant impact on functional measures of swallowing, eating and drinking and on self-reported QoL. Dysphagia can have long-term impacts on QoL, health and represent increased costs for treatment and hospital stays. Effective treatment options are needed to reduce the impact of dysphagia in all these areas.

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