Dysphagia in Head and Neck Cancer Patients in Kuwait

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Abstract

Introduction: Head and Neck Cancer (HNC) and its treatment often result in severe functional impairments, with dysphagia and related morbidities being serious and well-recognised complications in the acute, chronic and late stages. These complications contribute to a decreased quality of life and decreased overall HNC survival. An active surveillance of swallowing function using appropriate swallowing outcome measures is needed throughout the continuum of care. HNC dysphagia has not been studied previously in Kuwait.

Aims: The overall aim of this thesis is to investigate HNC dysphagia in Kuwait, with a long-term view to improve quality of life and reduce morbidity.

Methods and results: Five studies were conducted using different research designs. The first study aimed to investigate the prevalence of HNC dysphagia. The results suggest that dysphagia is not properly assessed and therefore may be under-reported. The second study explored the experiences and unmet needs of patients with HNC in Kuwait using qualitative interviews. The interviews revealed that patients often experience adverse feelings as a result of their functional and physical pain, and they employ different strategies to deal with their symptoms. Furthermore, the findings suggest that patients have substantial unmet informational and supportive care needs. Studies three to five aimed to further explore swallowing outcome measures in order to develop a multi-dimensional Swallowing Outcomes Package to systematically collect outcomes for HNC patients in Kuwait. The Package comprises: the MD Anderson Dysphagia Inventory (MDADI), a patient self-report tool, which was translated and culturally adapted and showed satisfactory psychometric properties. Diet scales, and a measure of swallowing performance (the 100mL Water Swallow Test (WST)). Preparatory work established the factor structure of the MDADI and the minimal clinically important difference for the 100mL WST.

Conclusion: This study identified gaps in HNC dysphagia management in Kuwait, and it highlights the importance of the systematic collection of swallowing outcomes to understand the impact of cancer treatments, monitor changes over time, and improve quality of life and decrease morbidity.

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Dedication

Dedicated to my mum, Ghanimah Habeeb

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction, contextual background and thesis overview

1.1 Introduction

This chapter is an introductory chapter to my thesis. I will first provide a general introduction to head and neck cancer (HNC) and HNC dysphagia, followed by a description of the geographical context of this thesis, Kuwait, including an outline of Kuwait's healthcare system and a survey of the HNC setting. The chapter concludes with an explanation of the purpose of the thesis and an overview of its contents.

1.2 Head and neck cancer

Tumours of the head and neck are the seventh most common cancers worldwide, accounting for 3% of all cancer types (Chow, 2020; Schindler, Mozzanica and Barbiera, 2019). Head and neck cancer (HNC) is a general term that describes malignancies occurring in the paranasal sinuses, nasal cavity, salivary glands, oral cavity (*i.e.*, lining of the lips, cheeks, gum, floor of the mouth, hard palate, two-thirds of the tongue and retromolar trigone), pharynx (nasopharynx, oropharynx, and hypopharynx), larynx (vocal cords and epiglottis) and head and neck lymph nodes (Argiris et al*.,* 2008; Devins et al., 2010; Gollin, 2015). Head and Neck Squamous Cell Carcinoma (HNSCC) is the most prevalent malignancy, accounting for approximately 95% of all HNCs (Argiris and Eng, 2003; Marur et al., 2010).

1.2.1 Epidemiology

Oral and oropharyngeal cancers

Taken together, oral and oropharyngeal cancers accounted for 2.5% of all cancers globally in 2018 (Bray et al., 2018). There are considerable geographical differences in the incidence of oral cancer. Two-thirds of oral cancer cases occur in low-income countries, with half of those cases in South Asia (Warnakulasuriya and Greenspan, 2020). Conversely, the oropharyngeal cancer rate is low in most Asian regions compared with Europe, North America, and developed areas of Australia and New Zealand (Louie et al., 2015; Miranda-Filho and Bray, 2020; Warnakulasuriya and Greenspan, 2020). Lip cancer, meanwhile, is considered to be common in some parts of Europe, Canada and Australia (Miranda-Filho and Bray, 2020; Warnakulasuriya and Greenspan, 2020).

Nasopharyngeal cancer

Although rare in most parts of the world, nasopharyngeal cancer (NPC) is prevalent in southern China and some parts of Southeast Asia. Intermediate risk areas include the Middle East and North Africa (Chang and Hildesheim, 2017), with Northern Europe and the United States being in the lowest-risk areas (Bing Tan, Stoker and Smeele, 2014). NPC is the 24th most common cancer worldwide, with approximately 86,700 newly-diagnosed cases and 50,800 deaths annually (Chang and Hildesheim, 2017). Patients with NPC tend to be young, especially in high-incidence areas—with the risk increasing after the age of 30, and peaking between the ages of 40 and 60 years. In low-risk areas, on the other hand, there are two peaks, the first occurring between 15 and 25 years, and the second between 50 and 59 years (Chang and Hildesheim, 2017; Lee, Yeung and Ng, 2009).

Laryngeal cancer

Cancer of the larynx accounted for 1.1% of new cancer cases, and 1% of all cancer deaths globally in 2018 (Bray et al., 2018). In most high-income countries the incidence and mortality rates of laryngeal cancer are decreasing (Olshan and Hashibe, 2017). The decline is related to the downturn in smoking, with which laryngeal cancer is strongly correlated (Mendenhall et al., 2009).

1.2.2 Risk factors

Historically, chewing or smoking tobacco, and increased alcohol consumption, are primary risk factors for the upper aerodigestive cancers. Viral infections such as Epstein-Barr virus (EBV) and, in recent years, the Human Papillomavirus (HPV) have also been identified as causative factors for HNSCC (Chang and Hildesheim, 2017; Chung and Gillison, 2009; Gupta and Johnson, 2014; Vokes, Agrawal, and Seiwert, 2015).

Tobacco and alcohol consumption

Smokers are at increased risk of developing oral, oropharyngeal, hypopharyngeal and laryngeal cancers (Vineis et al., 2004). Tobacco smoke contains various carcinogens that have been found to damage DNA, leading to cancer. Indeed, there is a dose-dependent relationship between tobacco use and the development of HNC. While the risk may decrease once the individual stops smoking in light or moderate smokers, unfortunately, it seems to persist in heavy smokers (Saunders, Coman and Guminski, 2014).

Tobacco chewing is an important risk factor for oral cavity cancers. Individuals who chew tobacco have an 80% higher chance of developing oral cavity cancers than those who do not, due to the extended and focused tobacco contact periods with the buccal mucosa (Saunders et al., 2014; Secretan et al., 2009).

Heavy alcohol consumption is a recognised risk for HNC, especially hypopharyngeal cancers (Anantharaman et al., 2011). Alcohol excess can also be associated with a delayed presentation of HNC, resulting in patients presenting with advanced tumours (Saunders et al., 2014). Furthermore, the combined behaviours of smoking and drinking synergistically increase the risk of developing HNC.

Viral infections

HPV comprises a group of viruses with more than 150 types that can be subdivided into high-risk and low-risk types for HNC (Gollin, 2015). The vast majority of HPV-associated HNCs (HPV+) are linked to HPV-16 (Devins et al., 2019), which is the leading cause of oropharyngeal cancer especially in North America, Europe, and other high-risk countries (Louie et al., 2015). Up to 70% of oropharyngeal cancers have HPV-DNA (Warnakulasuriya and Greenspan, 2020). Recently, HPV has also been suggested to play a role in the development of nasopharyngeal carcinomas, but its role in other anatomical head and neck sites remains unclear (Cottrill, Reilly and Coblens, 2020; Devins et al., 2019). The risk of getting HPV infection increases with increasing numbers of sexual partners. Affected individuals are most often men, at a younger age, with high socio-economic status, fewer coexisting conditions and lower rates of chronic tobacco and alcohol use than are those with non-HPV related cancers (Chow, 2020; Cottrill et al., 2020). Sudhoff et al., (2011) report that individuals who are non-smokers and non-drinkers but HPV16+ are 15 times more prone to develop oropharyngeal cancer than are smokers and drinkers.

EBV viral infection infects nearly all humans, usually in childhood and young adulthood, and is actively linked to NPC (Chang and Hildesheim, 2017). Despite its high prevalence, only a fraction of EBV-infected people develop cancer. Although the exact pathogenesis is as yet undetermined, it is expected that EBV-related cancers are caused by a combination of different factors such as dietary factors, genetics and other clinical factors (Bakkalci et al., 2020).

Other factors

Although tobacco, alcohol and exposure to certain viral infections are the primary risk factors for HNCs, there are other documented aetiological factors. Exposure to sunlight, especially for prolonged periods, is a known risk factor for lip cancers (Hashibe et al., 2017). Occupational exposure to carcinogens, including asbestos, wood dust, nickel, chromium and ionising radiation, is suspected to cause several HNCs (Steenland, Zahm and Blair, 2017). The role of diet and nutritional quality as risk factors for cancer development, and specifically HNC, is still inconclusive and challenging to determine. There is a general consensus, however, that reduced fruit and vegetable consumption is linked to higher risk for HNC, largely due to reduced intake of antioxidants (Bravi et al., 2021; Hashibe et al., 2017; McCullough and Willett, 2017; Saunders et al., 2014). Additionally, consumption of salt-preserved fish was found to be strongly associated with increased risk of NPC (Lee et al., 2009), with this association declining over time; in part due to increased awareness of its risk (Chang and Hildsheim, 2017). Host factors, such as genetic predisposition, have been suggested as contributory, especially for NPCs (Chang and Hildsheim, 2017; Hashibe et al., 2017).

1.2.3 Classification of primary HNC tumours

Determining the clinical and pathological stage of cancer is a foundation for diagnosing and treating the disease. The most commonly used classification for solid tumours is the TNM classification, a global system developed by the American Joint Committee on Cancer (AJCC) in collaboration with the Union for International Cancer Control (UICC; Cottrill et al., 2020). This classification offers information about the primary tumour size (T), lymph node involvement (N), and the presence or absence of distant metastasis (M). The TNM description will then determine the stage I (early) to IV (advanced) grouping of cancer.

T stages range from T1 to T4 (small tumour to large tumour, respectively). N staging is assigned N0 in the absence of regional lymph node involvement. N1-N3 describing increasingly extensive enlargement of involved lymph nodes. Finally, M status refers to the presence (M1) or absence (M0) of distant metastases beyond the locoregional glands. When the tumour size (T) or involvement of lymph nodes (N) cannot be assessed, they are usually described with an ‘x’ (Cottrill et al., 2020). Furthermore, ‘x’ also describes when the

primary tumour cannot be identified and there is a presence of a positive nodal involvement, suggesting an unknown primary status (Cheraghlou et al., 2018).

The 2018 eighth edition of the TNM staging system contained major modifications concerning the staging of HNCs; including the separation of pharyngeal cancers into three chapters (nasopharynx, oropharynx and hypopharynx), a separate algorithm for HPV-associated oropharyngeal tumours, and metrics concerning the depth of invasion for oral cancers (Cottrill et al., 2020).

Tumour classification and staging are useful for planning treatment, evaluating the effectiveness of treatments, providing a common language among the healthcare team, and predicting prognosis (Cottrill et al., 2020).

1.2.4 Prognosis

In general, the prognosis of HNC is poor, although the five-year survival rate varies depending on geographic region, epidemiological considerations, anatomical location and disease stage (Alhazzazi and Alghamdi, 2016; Chow, 2020; Miranda-Filho and Bray, 2020). Of the various patient factors affecting HNC prognosis, older age, lower performance status and having co-morbidities are contributors for worse survival (Stromberger et al., 2021).

One group of patients demonstrating better prognosis and survival rates, however, are those with HPV-associated (HPV+) oropharyngeal cancer. Patients with HPV+ oropharyngeal tumours have a five-year survival rate between 62-82% compared with 24-47% for non-HPV associated oropharyngeal cancers (Louie, Mehanna and Sasieni, 2015). This promising prognosis does not apply to patients who continue to smoke, however (Chen et al., 2020). For laryngeal cancers, the five-year survival rate varies between 56-68% (Gholizadeh et al., 2018). Survival is better in patients with localised tumours (77%) but only 33% for patients presenting with distant metastasis (Bradford et al., 2020). Similarly, patients with localised NPC have a 78% overall five-year survival rate, reaching up to 100%, whereas later stage tumours are associated with poor survival, as low as 26% (Tan et al., 2019). As for oral cancers, the five-year survival is 68%; Yang et al., 2020). Cancers of the hypopharynx have the least favourable five-year overall survival of 29%. This may be linked to late presentation of symptoms due to the nature of its anatomical location—a so-called silent site (Petersen et al., 2018). In addition, hypopharyngeal cancer is strongly associated

with heavy drinking, which can delay patients coming forward with their symptoms (Saunders et al., 2014).

1.2.5 Treatments

Treatment options with curative intent include surgery (either minimally invasive techniques or open surgery); surgery and adjuvant (chemo)radiotherapy; radiotherapy (RT) alone; or chemoradiotherapy (CRT; Ward and As-Brooks, 2014). More advanced disease is often treated with combination therapy. The choice of treatment depends on several factors: the site and stage of tumour, nodal status, cell type, the possibility of achieving satisfactory surgical margins and patient factors, e.g., age, general health status, and individual preference (Groher and Crary, 2016).

Generally, HNC management guidelines recommend that decisions are made by consensus within a multidisciplinary team (MDT) of healthcare professionals from different disciplines, including radiation oncologists, medical oncologists, surgeons, pathologists, specialist nurses and allied healthcare professionals, including the speech and language therapists (Karam and Wirtz, 2020). Each team member has a vital role in achieving optimal outcomes, including the restoration of function (Shabestari et al., 2017). Since patients are the pillars of these decisions, involving them and their caregivers in decision making is vital in order to achieve optimal individualised and patient-centred care (Dawson et al., 2020; Hamilton et al., 2016).

Surgical treatment

Surgical interventions aim to excise the primary tumour and ideally spare patients adjuvant treatments (Groher and Crary, 2016; Schindler, Mozzanica and Barbiera, 2019). This is not always attainable, however, as the majority of HNC patients present with locally-advanced large tumours, meaning that surgical resections may cause significant risk to organ function and/or result in appearance-altering defects. Often, neck dissection is performed to excise regional positive lymph nodes, or to eliminate the possibility of micro metastases (Schindler, Mozzanica and Barbiera, 2019; Sahovaler, Yeh and Fung, 2019). Adjuvant C(RT) therapy is typically required for those with advanced disease, treated with curative intent. New minimally invasive surgical techniques have emerged to preserve or reduce functional impairment, improve appearance and decrease the length of hospitalisation e.g., robotic

surgery and laser microsurgery (Chow, 2020; Lo Nigro et al., 2017; Sahovaler et al., 2019; Schindler et al., 2019).

(Chemo)Radiotherapy

Radiotherapy (RT) alone, with or without chemotherapy (C)RT can be used as a primary therapy for curative intent, or for palliation (Schindler et al., 2019). Given the complex anatomical location of head and neck tumours, the objective of treatment is to optimise delivery of radiation to the tumour while minimising exposure to surrounding healthy tissues, in order to avoid severe radiation-induced complications (Servagi-Vernat et al., 2015). RT techniques have evolved over the past decade, for example, Intensity Modulated Radiotherapy (IMRT), aim to mitigate the collateral damage to non-involved organs at risk by delivering radiation doses to the specific targeted areas (Wang and Eisbruch, 2016; Sahovaler et al., 2019).

In summary, all treatment modalities—surgery, radiotherapy and chemotherapy—can cause some alteration to form and function. In surgical interventions, the type of impairment can be predicted based on the type and extent of the intervention. With (C)RT protocols, however, impairments can be acute, or develop as a late side-effect. Since the main areas involved in local treatment are critical in swallowing, dysphagia (swallowing dysfunction) is common during and after treatment (Vidhyadharan, 2018).

1.3 Dysphagia and its consequences

Swallowing is a complex mechanical interaction between three anatomically separated areas: the oral cavity, pharynx and oesophagus. Typically, swallowing has four sequential voluntary and involuntary phases: oral preparatory phase, oral phase, pharyngeal phase and finally the oesophageal phase (Siwiec and Babaei, 2020). This process involves six cranial nerves and more than 30 muscles, thus requiring high levels of coordination between sensory input and motor function (Ebersole and Moran, 2020). Damage to the relevant nerves or muscles may result in dysphagia. Dysphagia can result in impaired safety and efficiency.

An *unsafe* swallow is characterised by the passing of the bolus into the larynx, above (penetration) and below (aspiration) the vocal folds (Rosenbek et al., 1996; Rofes et al., 2011). Aspiration can lead to malnutrition, dehydration and may also result in pulmonary complications such as aspiration pneumonia (Szczesniak et al., 2014). Individuals with HNC are at higher risk of developing aspiration pneumonia as they suffer from acute and chronic oral complications such as mucositis, xerostomia, and trismus which may limit or constrain their ability to keep an optimal oral hygiene due to pain or reduced mouth opening. Maintaining good oral care has been reported to lower oral bacteria, that may lead to pneumonia, especially in vulnerable groups (Nishizawa, 2022). It has been suggested that poor oral hygiene is a risk factor for aspiration pneumonia (Kawai et al., 2017; Reddy et al., 2021).

Swallowing *efficiency* refers to timely movement and/or residue-free bolus passage from the oral cavity to the stomach (Rofes et al., 2011). Substantial inefficiency can lead to malnutrition and dehydration. The presence of dysphagia may also increase hospital stay and treatment cost (Attrill et al., 2018). All these complications are major contributors to reduced quality of life (QOL).

Both HNC itself, and its treatment may cause dysphagia. The dysfunction in the pre-treatment phase depends on host and tumour specific factors, while post-treatment dysphagia is heavily influenced by the type of intervention.

1.3.1 Pre-treatment dysphagia

The incidence and severity of pre- treatment dysphagia depends on tumour location and stage, and is caused by sensory malfunction and /or the mechanical impact of the tumour itself. Pre-treatment dysphagia ranges from 30 to 52% (Kristensen, Isenring and Brown, 2020; Platteaux et al., 2010), with hypopharyngeal cancer patients presenting with the worst swallowing function (Raber-Durlacher et al., 2012). Pre-treatment aspiration is less well studied. Most studies concerning aspiration refer to the results of treatment (Lal et al., 2014). Nonetheless, a meta-analysis reported the frequency of aspiration at pre-treatment to be 8.4% (de Toledo et al., 2019). The highest rates of pre-treatment aspiration occur in patients with pharyngeal and laryngeal cancers (Logemann et al., 2006; Pauloski et al., 2000; Stenson et al., 2000).

1.3.2 Dysphagia following surgical treatments

Surgical intervention may involve resection or reconstruction of swallowing-related structures, leading to changes in the swallowing-related anatomy, and potential neural damage (Groher and Crary, 2016). Several variables contribute to the type and severity of swallowing impairment, including the extent of surgical resections and the type of reconstruction (Arrese and Schieve, 2019). A systematic literature review (Kreeft et al., 2009) found that swallowing function is disrupted immediately after surgery for advanced oral and oropharyngeal cancers, and despite slight improvements over time, swallowing remains disordered for up to one year post-operatively. Table 1 summarises some of the possible swallowing impairments as a consequence of selected open surgeries.

In general, larger resections result in greater swallowing function impairment, but the most substantial impacts on swallowing result from resections of the oral tongue, tongue base and larynx, since these structures are vital in bolus formation and transit, and airway protection (Raber-Durlacher et al., 2012). The prevalence of aspiration is between 12% to 25% in post-surgical patients, up to one year (Hutcheson and Lewin, 2013; Kreeft et al., 2009). Minimally-invasive surgeries are associated with faster recovery and less pain amongst other benefits. Unfortunately, however, these techniques do not eradicate the risk of dysphagia (Hansen et al., 2018).

Table 1 Common swallowing disorders resulting from some open head and neck surgeries

Site	Effect on swallowing
Oral (Arrese and Schieve, 2019; Groher and Crary, 2016; Manikatan et al., 2009)	- Difficulty manipulating or moving the bolus in the oral cavity. - Reduced lingual strength and range of motion (ROM). - Impaired mastication. - Nasal regurgitation. - Increased oral transit time. - Increased pharyngeal residue. - Increased oral residue. - Disruption to hyolaryngeal elevation resulting in poor airway protection and risk of aspiration.
Oropharyngeal (Arrese and Schieve, 2019)	- Reduced base of tongue to pharyngeal wall contact. - Velopharyngeal incompetence, nasal regurgitation and reduced pharyngeal contraction. - Delayed/reduced swallow reflex. - Reduced swallowing efficiency. - Risk of aspiration.
Hypopharynx and larynx (Arrese and Schieve, 2019; Groher and Crary, 2016; Starmer, 2019)	- Reduced pharyngeal pressure leading to inefficient bolus propulsion. - Reduced laryngeal sensation. - Reduced airway protection. - Risk of aspiration. - Reduced upper oesophageal sphincter opening.

1.3.3 Dysphagia following non-surgical treatments

RT and CRT can have significant and long-lasting effects on swallowing which are well documented in the literature (Murphy and Gilbert, 2009; Russi et al., 2012; Wall, Ward, Cartmill and Hill, 2013). Table 2 reports the common swallowing impairments post (C)RT regimens.

Many patients suffer from significant acute and chronic treatment complications that impact on eating and drinking. Acute complications include neurosensory changes in the senses of smell and taste (dysgeusia), mucositis (inflammation of the mucous membrane), salivary changes, odynophagia (painful swallow) and oedema (Arrese and Schieve, 2019; Raber-Durlacher et al., 2012; Schindler et al., 2015). Chronic complications include

xerostomia (dry mouth, which can also be acute), lymphedema (collection of fluid beneath the skin), and fibrosis (scaring of connective tissues); including trismus (reduced mouth opening) (Kearney and Cavanagh, 2019; Epstein et al., 2012; Murphy and Gilbert, 2009; Stubblefield, Manfield, and Riedel, 2010). Late onset dysphagia is also a possibility in patients treated with (C)RT, developing, or progressing in disease-free patients in the years following treatment completion (Hutcheson et al., 2013; Kearney and Cavanagh, 2019).

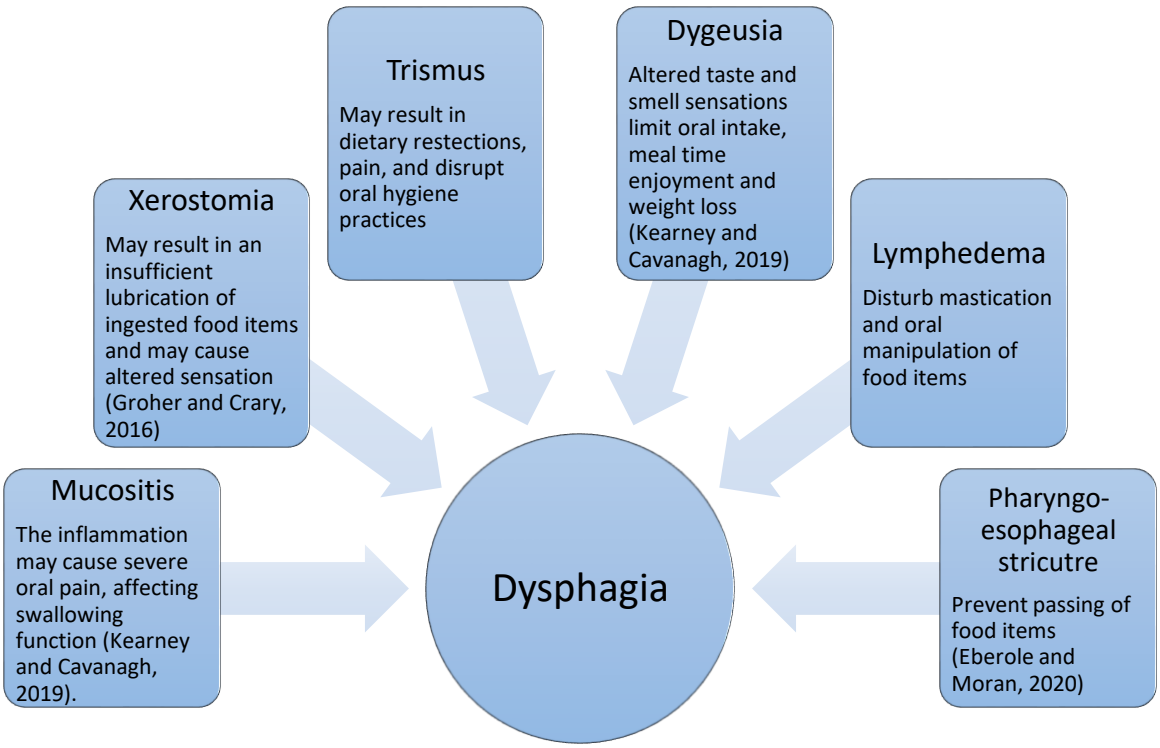
The effects of radiation-induced complications of dysphagia are shown in Figure 1.

Table 2 Common swallowing impairments resulting from (Chemo)radiotherapy

Swallowing phase	Impairments
Oral phase (Groher and Crary, 2016)	- Trismus and reduced jaw ROM. - Reduced lingual strength and ROM. - Increased oral residue - Impaired bolus formation, transportation and increased oral transit time.
Pharyngeal phase (Servagi-Vernat et al., 2015; Starmer, 2019)	- Reduced tongue base retraction. - Impaired velopharyngeal closure. - Delayed swallow reflex. - Reduced pharyngeal contraction. - Reduced laryngeal elevation and laryngeal vestibule closure. - Reduced/delayed upper oesophageal sphincter opening. - Reduced airway protection.

ROM: Range of motion

Figure 1 Radiation-induced complications and their impact on swallowing



Aspiration is common following RT/CRT treatment, and can lead to serious health complications if pulmonary infection develops. Aspiration can sometimes be silent, and therefore may be underestimated and underreported, making it difficult to determine its true incidence (Hutcheson and Lewin, 2012; Nguyen et al., 2006; Patterson et al., 2018). Nguyen et al. (2006) reported an aspiration rate of 17% prior to CRT, substantially increasing to 59% post-treatment, although they only recruited patients who complained of a swallowing problem. Elsewhere, Patterson et al. (2014) found the aspiration incidence increased from 14% pre-treatment to 28% one year post-treatment in a consecutively recruited cohort, including those not reporting a problem. Twenty-two percent of this group continued to aspirate at six years post-treatment (Patterson, McColl, Carding and Wilson, 2018).

1.4 Dysphagia management

Identifying functional impairments, including swallowing difficulties, is the responsibility of the whole MDT, however the main role relies on the Speech and Language Therapists (SLTS; ASHA, 2020; Clarke et al., 2016). SLTs are trained healthcare professionals who are specialised in the management of swallowing difficulties. SLTs play an integral role in optimising functional outcomes and improving QOL throughout the HNC continuum of care (Clarke et al., 2016; Platteaux et al., 2010; Lo Nigro et al., 2017). They dedicate time to identify dysphagia symptoms through different assessment methods, and manage symptoms through swallowing therapy to preserve or restore muscle function, behavioural or compensatory strategies (e.g., dietary changes, posture changes) or by recommending alternative methods of feeding (e.g., feeding tube; Hansen et al., 2018).

Early involvement of SLTs in the management of HNC patients is encouraged, starting before treatment. SLTs assess the specific swallowing-related needs and conduct a comprehensive assessment to evaluate swallowing function (ASHA, 2020). Moreover, this pre-treatment session is essential for rehabilitation planning, and to establish pre-treatment functioning to compare change over time. In addition, the SLT provides patients and caregivers with information regarding possible treatment side-effects, offers realistic expectations regarding their individual case, answers their questions, and may recommend prophylactic swallowing exercises to preserve swallowing or reduce impairments. In other words, SLTs promote active participation by patients and their caregivers (Clarke et al., 2016). This support continues throughout treatment, during follow-ups, and throughout survivorship.

1.4.1 Timings of swallowing assessment

At pre-treatment, an SLT typically meets with the patient and their family to discuss the potential effects of the proposed cancer treatment on their function. Pre-treatment involvement allows the therapist to establish baseline swallowing outcomes (Patterson and Wilson, 2011), assess any pre-treatment dysphagia symptoms, and identify patients who are at high risk of developing dysphagia. Baseline swallowing status can be predictive of future swallowing outcomes (Lazarus, 2000; McColloch, Carroll, and Magnuson, 2010; Patterson et al., 2014). Moreover, pre-treatment meetings with the patients provides an opportunity to discuss swallowing impairments that may occur during or after treatment

in addition to encouraging shared clinical decision making (Elwyn et al., 2012) (e.g. prophylactic feeding tube placement and diet modification; Hutcheson and Lewin, 2012), and to provide a patient-centred management plan, which helps give patients realistic expectations regarding their swallowing prognosis (Brockbank, Miller, Owen, and Patterson, 2015; Lazarus, 2000).

Swallowing ability must be monitored continually to identify changes that occur throughout and after treatment. For surgical patients, early assessment post-operatively is beneficial, but the decision to re-introduce oral intake must be made in consultation with the treating surgeon (Groher and Crary, 2016) taking account of mucosal healing timescales, which may vary considerably between primary and salvage surgery (i.e., following failed nonsurgical management).

For patients treated with (C)RT regimens, swallowing should be assessed frequently during treatment in order to evaluate acute toxicity and swallowing safety, and to encourage patients, as far as is possible, to maintain oral feeding and adherence to swallowing exercises so as to avoid muscle disuse atrophy (Carnaby-Mann et al., 2012; Cousins et al., 2013; Hutcheson et al., 2013; Shune et al., 2012). This evaluation can also inform decisions regarding patients' needs during this critical stage, e.g., in respect to pain management and oral mucositis (Villegas, 2018). Patients should be informed of the possibility of late onset dysphagia, and its signs and symptoms, so that they are best positioned to detect changes and arrange follow-up as soon as possible.

1.4.2 Predictive factors

Understanding the predictive factors that affect swallowing is valuable, allowing for an early identification of high-risk patients and those who may require closer monitoring. Some empirical evidence highlights specific clinical and demographic dysphagia risk factors.

Tumour site

Several studies have investigated the effect of the tumour site on swallowing. Patients with tumours in the hypopharynx and larynx were found to be most frequently aspirating at baseline (Logemann et al., 2006; Pauloski et al., 2000; Stenson et al., 2000). This may be attributed to reduced airway protection due to obstruction and/or sensory changes (Jamal et al., 2017). Findings from other research groups confirmed that patients with

hypopharyngeal tumours had the poorest swallowing, both at baseline and post-treatment (Frowen et al., 2009). Patients with laryngeal tumours have better swallowing function during (C)RT treatment, recorded by self-report and instrumental tests, than patients with oropharyngeal tumours (Logemann et al., 2008; Rinkel et al., 2016).

Tumour size

Advanced tumours have a greater negative impact on swallowing function at baseline and post-treatment according to several studies using patient self-report (Costa-Bandria et al., 2008; Dwivedi et al., 2012; Goepfert et al., 2016 and Silveira et al., 2015). This was confirmed using instrumental assessments and found to be independent of tumour site or treatment modality (Frowen et al., 2009; Goepfert et al., 2016; Lango et al., 2014).

Treatment type

There is a general agreement that single modality treatment causes fewer side-effects, and therefore results in better swallowing outcomes, than multiple modality. For example, Logemann et al. (2008) found that the frequency and severity, but not the pathophysiology, of dysphagia are increased for patients receiving CRT compared with patients receiving RT alone. Each modality has its own toxicities but, when combined, chemotherapy increases radiation toxicity (Forastiere et al., 2001).

The mode of radiotherapy delivery may also affect swallowing outcome. Patients treated with radiation alone, specifically IMRT, show favourable swallowing outcomes compared with patients treated with conventional radiotherapy (Kraaijenga et al., 2015). Radiation dosage also plays a role in swallowing outcome, as it can predict short- and long-term swallowing problems at three and twelve months, up to six years post-treatment (Patterson et al., 2011; Patterson et al., 2018). Surgical interventions also introduce swallowing problems, which differ based on the type of surgical procedure, whether an adjuvant treatment is required or not and the type of surgical resections (Groher and Crary, 2016).

Sex

It is difficult to determine the role sex plays in swallowing problems in the HNC population as it is predominantly a ‘male disease’. Recruiting large enough numbers to explore this factor is a challenge. One study found a significant correlation between age, gender and

swallowing performance, determining that younger patients and males had a better swallowing performance (Patterson et al., 2009). Interestingly, however, other studies examining swallowing-related quality of life (QOL) in specific tumour sites (i.e., oropharynx) or mixed HNC groups (Goepfert et al., 2016; Lango et al., 2014; Rinkel et al., 2016 and Wan Leung et al., 2011) have found no gender or age effects on swallowing-related QOL (Dwivedi et al., 2011; Iseli et al., 2009; Wilson et al., 2011).

Other factors

The influence of other factors has been investigated in a small number of studies. Some found that pre-treatment swallowing function can predict short-term (three- and six-months post-treatment) and long-term (one year) swallowing outcomes (Frowen et al., 2009; Patterson et al., 2011). Alcohol (Frowen et al., 2009; Silveira et al., 2015) and persistent smoking (Goepfert, 2016; Silveira et al., 2015) were also found to have an impact on swallowing in subjective and objective measures. Other factors reported to affect swallowing function include gastroesophageal reflux (Pezdirec, Strojan and Boltezar, 2019), the presence of a nasogastric tube (Silveira et al., 2015), and retaining the G-tube post-surgery (Iselie et al., 2009). Living in rural areas (Frowen et al., 2009) was also found to impact swallowing function post-treatment. This could be related to difficulty maintaining follow-ups due to travel limitations.

Both clinical and demographic characteristics should therefore be considered when evaluating HNC patients to identify patients who are at high risk of developing dysphagia at the early stages. Using different types of assessment methods, SLTs can identify and determine the type and nature of the swallowing problem and its effect on QOL, to inform their recommendations.

1.4.3 Swallowing assessment options

Swallowing is multifactorial, and thus it requires multi-dimensional assessment to form a holistic view on the nature and severity of dysphagia. The principles of dysphagia assessment in HNC are similar to dysphagia assessment in different aetiologies. Commonly-used methods to collect these data are: 1) Patient-reported dysphagia, and 2) impairment-based methods, including Clinical Swallowing Evaluation (CSE), and Instrumental assessments. Table 3 provides a summary of some of the advantages and disadvantages of these methods.

Patient-reported dysphagia

Patient-reported outcomes (PROs) provide an understanding of the lived experience of dysphagia and its impact on Health-related quality of life (HR-QOL). They allow meaningful outcome measurement of interventions, systematic identification of patients who require further assessments and the selection of appropriate, patient-centred therapy goals (Speyer et al. 2011). Options for HNC are the administration of QOL questionnaires that include items on swallow impairment and dysphagia-related symptoms such as painful swallowing, taste changes, coughing while eating/drinking (Arrese et al., 2019; Holländer-Mieritz et al., 2019; Peng et al., 2018) or dysphagia-specific questionnaires. In Chapter 4, I will expand on dysphagia-specific questionnaires.

PROs do not have a strong relationship to measures of swallowing impairment (Patterson, 2019). Patients may not always be aware of their swallowing difficulties (Charters et al., 2020; Kirsh et al., 2018), especially after treatment when there is a higher chance of silent aspiration (Raber-Durlacher et al., 2012). Some patients may present with significant impairment, but without substantial impact on their lifestyle. Suggesting that patients adjust to their ongoing difficulties regardless of their ongoing difficulties (Cartmill et al., 2012). Therefore, despite not having a strong relationship to measures of swallowing impairment, PROs may relate better to long-term outcomes.

Clinical swallowing evaluation

A CSE is often the first step in dysphagia assessment (Lazarus, 2000; Patterson and Wilson, 2011; Speyer et al., 2021). A CSE is a structured assessment that combines information from different sources to provide a preliminary understanding of the patient's swallowing ability. It usually consists of a full chart review, followed by a comprehensive case history to identify any possible factors that may compromise swallowing function. For example, many patients with HNC have poor pulmonary health status at the time of diagnosis. It is estimated that around 26% of HNC patients present with Chronic Obstructive Pulmonary Disease (COPD) at the time of diagnosis (Eytan et al., 2018; Gottlieb et al., 2020) which is associated with dysphagia (Dawod et al., 2015). The careful review of the case history is usually followed by cognitive assessment, cranial nerve/oral-motor examination, pharyngeal, laryngeal and pulmonary function evaluations, nutritional status, and then swallow trials observing different food items and consistencies (Garand et al., 2020; Menon

and Raj, 2018). The patient's ability to orally prepare and move the bolus to the pharynx, estimating swallow timing and detecting signs and symptoms of aspiration are important observations (Logemann, 1998; Patterson and Wilson, 2011).

The CSE is followed by an integration of the collected information and weighing up of the risks in order to formulate a management plan (Speyer et al., 2021). For example, patients planned to be treated with multiple modalities are at higher risk of complications than patients facing single modality treatment. Moreover, if results indicate the need for a further assessment, such as a high suspicion of aspiration, than an instrumental assessment will follow.

Instrumental swallowing assessments

Instrumental assessments are regarded as gold-standard assessment methods, since they allow direct observer-rated assessment of swallowing pathophysiology. The most commonly-used methods are 1) Videofluorosopy, a dynamic radiological examination of swallowing performed in a joint clinic with a radiologist or radiographer and an SLT, and 2) Flexible Endoscopic Evaluation of Swallowing (FEES), usually performed by an SLT (FEES; Patterson and Wilson, 2011). Both methods are reliable and valid. In both methods, food items of different consistencies (e.g., thin liquid, puree and solid consistencies) are given to the patients. Assessments are recorded for playback and detailed analysis. Typically this would include rating scales of swallowing parameters such as the Penetration Aspiration Scale (PAS), Dynamic Image Grade of Swallow Toxicity (DIGEST) and the MBS impairment Scale (MBSImp) (Martin-Harris et al., 2008; Hutcheson et al., 2017; Patterson, 2019; Rosenbek et al., 1996).

Instrumental assessments allow the observer to measure the nature of the physiological impairment, and the safety and efficiency. The detection of any aspiration is important, since this determines whether the patient may safely be allowed to continue with oral intake, and whether such intake is likely to be sufficient to maintain hydration and nutrition. Overall, instrumental assessments are useful for supporting differential diagnosis and determining suitable therapeutic strategies to improve the dysfunction (Allenm Clunie and Winiker, 2021; Lazarus, 2000; Logemann, 1998; Patterson and Wilson, 2011).

Although instrumental assessments are valuable in the assessment of swallowing, they are costly, and not always accessible as they require special equipment and trained personnel (Patterson, 2019), a factor that also precludes their very regular repetition.

Table 3 Advantages and disadvantages of the common swallowing assessment methods

Assessment		Advantages	Disadvantages
Patient-reported (Patterson and Wilson, 2011; Raber-Durlacher et al., 2012).		- Captures patient's perspectives. - Reflect the impact of impairments on daily activities. - Easy to administer.	- Weakly correlated with physiological impairments - Mediated by mood
Clinical Swallowing Evaluation (Garand et al., 2020; Langmore and Logemann, 1991; Speyer et al., 2021).		- Performed at bedside and during mealtimes. - More normal and representative of swallowing. - Low-cost. - Determine the patients readiness for instrumental assessments.	- Does not provide information on the anatomy of the pharynx and larynx. - There is a variability in practice between clinicians. - Does not provide objective information on the oropharyngeal and pharyngeal phases of swallowing. - Does not have 100% sensitivity and specificity for aspiration although its aims are not limited to the detection of aspiration.
Instrumental assessments (Patterson, 2019; Patterson and Wilson, 2011; Starmer, 2019).	FEES	- No radiation exposure. - Can be performed with 'normal' food and liquid test items. - Can be performed at bedside. - Visualisation of the pharynx anatomy and physiology.	- Requires special equipment and personnel. - No visualisation of the oral and oesophageal swallow phases. - No visualisation during swallowing.

	- Detect penetration and aspiration. - Can be combined with voice assessment. - Can be performed with non-oral patients to assess secretion management. - Can determine the suitability of postural changes.	
VFS/MBS	- Visualisation of all three swallowing phases. - Can detect penetration and aspiration. - Can determine the suitability of postural changes.	- Costly and requires special equipment and personnel. - The addition of barium to test items alters the consistency. - Immobile equipment. - Radiation exposure.

1.5 Summary

In summary, HNC and its treatment often result in severe functional impairments, with dysphagia and related morbidities being serious and well-recognised complications in the acute, chronic, and late stages. It is appreciated that these complications are contributors to decreased QOL and increased social isolation; however, these complications are critical in determining other key factors such as overall survival. Dysphagia is reported in about 60% of HNC patients treated with (C)RT (Shune et al., 2012), and if not recognised at the appropriate time it can lead to other morbidities and possibly mortality. It has been reported that malnutrition, a probable consequence of dysphagia, occurs in about 70% of HNC patients, and is related to interruption of treatment, poorer survival outcomes (Hung et al., 2020), increased hospital admissions and longer length of hospital stay (Hazzard et al., 2017). Moreover, aspiration pneumonia accounts for 19% of non-cancer-related deaths in HNC (Reddy et al., 2020; Szczesniak et al., 2014).

With the advances in HNC treatments, and the increased number of HNC survivors, dysphagia remains a long-term serious sequela, with late onset dysphagia being common. This demands active surveillance of swallowing function to identify and manage symptoms

before they progress and result in other serious complications. This surveillance requires a multi-disciplinary team effort, in which the role of the SLT is indispensable. Indeed, the SLT's role begins prior to treatment initiation and throughout the continuum of care in order to maximise functional outcomes, reduce comorbidities, manage symptoms and improve QOL. Patient counselling, education and the identification and management of swallowing impairments are all within the scope of the SLT. Swallowing assessments should be conducted systematically, from baseline to post-treatment, allowing for the early identification of high-risk patients, thus preventing or reducing dysphagia and its devastating consequences.

To improve outcomes, the SLT should be present at the treatment facility to follow-up with the patients and tailor rehabilitation programmes in order to provide patient-centred care. This is not always achievable, however, especially in contexts where the SLT profession is still in its infancy. In Kuwait, for example, the SLT profession is relatively new, especially in respect of dysphagia management for HNC patients.

In the following sections, more information will be provided regarding the background of Kuwait and the SLT profession.

1.6 Geographical context of the thesis

Kuwait has a surface land mass of 17,818 km^2 and is located within the Middle Eastern region of Asia. Kuwait's population is estimated to be 4.4 million (Central Statistical Bureau, 2019), with the majority (70%) of the population being expatriates. The official language is Standard Arabic, but its use is limited to education and official media reports. The Kuwaiti Arabic (dialect) is used in everyday life, with a variety of other different Arabic dialects, and the English language is widely understood as it is considered to be a second language and the lingua franca for the majority of the non-Arabic speaking populations.

1.6.1 Healthcare in Kuwait

Kuwait is divided into six health regions: Capital, Hawali, Ahmadi, Jahra, Farwaniya and Al-Sabah. Each health region manages at least one general hospital and a number of primary health centres and specialised clinics. The Ministry of Health monitors all governmental and private clinics. In Kuwait, the health system is based on three levels of health care delivery: primary health centres (e.g. general practitioner services), secondary health

centres (e.g. general hospitals with different departments) and tertiary (specialised) health care centres (e.g., Kuwait Cancer Control Centre).

Kuwait Cancer Control Centre

The Kuwait Cancer Control Centre (KCCC) is a governmental centre affiliated with the Ministry of Health (MOH) in Kuwait. It is the only oncology centre in the country and was founded in 1968 (KCR, 2013; Kuwait Cancer Centre). The centre provides care for cancer patients and includes four main buildings: 1) Hussain Makki Juma'a for Specialised Surgeries, 2) Shiekha Badriya Al-Sabah Medical Oncology and Stem Cell Transplantation, 3) Faisal Sultan Centre for Radiology and Radiotherapy and 4) Yacoub Behbehani Laboratory Building and Bone Marrow Transplantation Centre.

1.6.2 Speech and language therapy services in Kuwait

Education and training and employment

In Kuwait, the profession of speech and language therapy can be traced back to 1993 (Alshatti et al., 2011 cited in: Alsaad, 2018). Back then, Kuwait had no qualification requirements for the SLT profession (Alshatti et al., 2011 cited in: Alsaad, 2018); i.e. individuals with phonetics, education and psychology backgrounds could work as SLTs. Due to demand for speech, language, swallowing and voice disorders services, the Kuwaiti government offered scholarship opportunities for students to qualify overseas. Additionally, in 2003 the Department of Communication Sciences at Kuwait University offered its first Communication Disorders programme. The course follows the British model; a four-year bachelor's degree including clinical placements. By the year 2015, there were 95 graduates (Alsalmi and Mayo, 2016 cited in: Alsaad, 2018). After qualifying, SLTs can work in clinical or educational settings. SLTs working in clinical settings (governmental or private) are required to obtain a licence to practice from the Ministry of Health (MOH).

Service locations

In the government sector, SLT services are provided in two major hospitals: The Physical Medicine and Rehabilitation Hospital (PMRH), and Shaikh Salem Al-Ali Speech and Hearing Centre, with some clinics within medical centres across the country. The two main hospitals provide different SLT services, with the PMRH being a multi-disciplinary hospital covering

a wider group of patients who need different rehabilitation services (e.g. speech and language therapy, physical therapy and occupational therapy).

Currently, the PMRH has 40 full-time SLTs, providing services for patients with different developmental and acquired speech, language, voice and swallowing disorders. Out of these 40, six SLTs work with adults, but only three have an exclusively adult caseload. The PMRH has a contract with different hospitals/centres to provide SLT services, because most of the major centres do not have SLT departments. Currently, one SLT visits the KCCC twice a week to assess and manage cancer patients, mainly HNC patients.

SLT – dysphagia services at the KCCC

The official dysphagia service started at the KCCC in 2014. At that time, the SLT would visit the centre once a week. Usually, the SLT would see in-patients, and occasionally out-patients referred by other clinicians. This was not ideal, however, because many patients would be overlooked, which may result in devastating and unnecessary negative outcomes. The service was interrupted briefly in 2018 and 2019 due to reduced number of SLTs. As of early 2020, however, the service has commenced again with an increase in the number of visits to twice per week in recognition of the high demand and need for the service. At the beginning of 2021, meanwhile, work commenced to set up a dysphagia unit at the KCCC so that SLTs could be assigned to work there full-time. This initiative was highly praised by key stakeholders, including the director of the centre and the HNC oncologists.

At the moment, not all HNC patients are referred to an SLT before treatment. Indeed, the majority of patients are only referred once they report dysphagia symptoms. From 2014 to 2019 the system for referral to an SLT at the KCCC was tedious and required a dietician or a nurse to suspect swallowing difficulties and for them then to ask a physician to refer the patient to the SLT.

1.7 Purpose of the thesis

The Kuwait Cancer Registry releases an annual report of the incidence of cancer in Kuwait, providing an extensive review on the top ten diagnosed cancers for both males and females. HNC does not fall into that category. Additionally, only two papers (Parikh and Ghamrawi, 1987; Morris et al., 2000) have been published on the incidence of HNC in Kuwait. These two studies are more than 20 years old, however and it is likely that the

nature of HNC in Kuwait has changed in that time, not to mention the enhancements in the treatment modalities provided for this population. It is therefore important to conduct a more recent study to estimate the impact of HNC dysphagia in Kuwait.

For this client group, early detection of dysphagia and aspiration is critical to reduce or eliminate morbidities. SLT services are not available on a daily basis at the KCCC due to limited human resources. This shortage risks under diagnosis and treatment of HNC dysphagia, affecting the quality of care. Furthermore, as patients are not necessarily aware of their swallowing difficulties, this could lead to major health risks. Moreover, no HNC-swallowing-specific outcome measures (PROs) are available to assess patients' concerns and QOL. This could also lead to lack of understanding of the disease burden on patients, and limit monitoring of symptom changes over time.

1.7.1 Key aims and objectives

The overall aim of this research project is to investigate dysphagia in HNC patients in Kuwait, with a long-term view to improve quality of life and reduce morbidity.

Objectives:

1. Investigate the prevalence of HNC and dysphagia in Kuwait.
2. Assess the unmet needs of HNC patients experiencing dysphagia.
3. Explore swallowing outcome measures to develop a multi-dimensional swallowing assessment package appropriate for application to HNC patients in Kuwait in the short to medium-term.

1.8 Thesis overview

As there is a lack of research on this topic in Kuwait, and given the complex nature and importance of head and neck cancer dysphagia, I decided to explore different approaches and employ different methods to achieve the aim and objectives rather than following one in depth approach.

This thesis will follow a manuscript style for chapters 2 – 6, as each chapter represents a different study. Studies in this thesis took place concurrently and not consecutively.

- Chapter 1: (this chapter): A general introduction, background and thesis overview.

- Chapter 2: Describes the prevalence of dysphagia in HNC patients in Kuwait, and compares it with the available literature internationally.
- Chapter 3: Reports on the experiences and unmet needs of HNC patients with a focus on dysphagia.
- Chapter 4: Details the patient self-report of swallowing-specific QOL, specifically the translation and adaptation of the MD Anderson Dysphagia Inventory.
- Chapter 5: Concerns disease-related dietary restrictions. It compares two diet assessment scales from clinicians' perspectives: The Functional Oral Intake and the Performance Status Scale.
- Chapter 6: Addresses a simple and widely-used observer-rated swallow assessment, the timed 100mL Water Swallow Test, and establishes for the first time its minimally clinically important difference using three approaches.
- Chapter 7: Describes a prototype of swallowing outcomes measures for HNC patients.
- Chapter 8: General discussion and conclusion.

Chapter 2: Challenges of head and neck cancer and dysphagia in Kuwait

This is the first results chapter of my thesis. It includes a study that aimed to investigate the prevalence of head and neck cancer (HNC) and dysphagia in Kuwait.

2.1 Literature review

Cancer is a major public health issue in Kuwait; cancer is the second major cause of death after cardiovascular diseases, accounting for one-fifth of mortality (Kuwait Cancer Registry annual report, 2013). Prostate cancer, colorectal cancer, lung cancer and leukaemia are among the 10 most common cancers in males, whereas breast cancer, thyroid cancer, colorectal cancer and cancer of the corpus uteri are among the 10 most common cancers in females (Kuwait Cancer Registry annual report, 2014). Worldwide, HNCs account for 3% of all malignancies (Chow, 2020; Schindler et al., 2019). In the Middle East and North Africa (MENA) region, newly diagnosed cases of oral and oropharyngeal cancers accounted for 2% of all malignancies in 2012, with a mortality rate of 1% (Kujan, Farah, Johnson, 2017). The MENA countries share a number of similarities in terms of environment, culture and economy. Kuwait and the Gulf Cooperation Council (GCC) countries are among the 23 MENA countries.

2.1.1 Head and neck cancer in Kuwait – the scope of the problem

In spite of the overwhelming impact of HNCs and their associated morbidities, there is an extreme paucity of studies reporting on HNCs in Kuwait. A 12-year review conducted in 1978 investigating nasopharyngeal cancer (NPC) incidence in Kuwait showed that it was then the most common HNC (18%), followed by laryngeal cancer (15%) and hypopharyngeal cancer (8%) (Parikh and Ghamrawi, 1987). In a later study investigating the epidemiology of lip, oral and pharyngeal cancers from 1979 to 1988, NPC remained the leading HNC (25%), followed by salivary gland tumours (24%) and hypopharyngeal cancer (14%) (Morris, et al., 2000). Mirroring similar trends worldwide, HNCs were more common in males than in females. The age at diagnosis, however, was relatively young (with the most frequent age range being 41-50 years). On the basis of projections using the

GLOBOCAN data from 2012, (a project of the International Agency for Research on Cancer [IARC]; https://gco.iarc.fr), it is estimated that the cases of oral and oropharyngeal cancers in Kuwait will double by 2030 (Kujan, et al., 2017). A plausible explanation for this growth is an increased exposure to environmental risk factors, especially tobacco and alcohol. The projected increase may also be attributed to human papilloma virus (HPV) infection, which is highly associated with oropharyngeal cancer, especially in North America and Europe.

2.1.2 Risk factors

Tobacco use, alcohol consumption and viral infections are well-known risk factors associated with HNC as discussed in Chapter 1. Kuwait has a high prevalence of smoking among males (41%). Its prevalence among females is reported to be approximately 5% (Al-Zalabani, 2020). However, low smoking prevalence rates among females may be an under-representation because, despite cultural changes, tobacco smoking by women is still frowned upon. On the basis of the GLOBOCAN and World Health Organisation (WHO) data, it is estimated that smoking was associated with 40% of HNCs in males and females diagnosed in 2018 in Kuwait (Al-Zalabani, 2020). Despite the high prevalence of smoking in Kuwait, the prevalence of laryngeal cancer – highly associated with smoking – has not been previously reported.

In Kuwait, HPV-16 prevalence in low- and high-grade cervical lesions is 18% and 33%, respectively. However, its prevalence in healthy individuals and HNC patients remains undetermined (Bruni et al., 2019). Although there is limited evidence on the association of HPV with HNC in the MENA region, a meta-analysis based on the available reports estimated that the pooled prevalence of HPV-associated HNCs (Asiri, Obeid and Alhamlan, 2020) – mostly involving the salivary glands and tonsils – was 19%. This prevalence rate is lower than the global prevalence rate of HPV-associated HNCs (approximately 30%; Etyan, Blackford, Eisele and Fakhry, 2018) but expected to increase over time, especially given the regional absence of HPV-vaccination programmes.

Both studies on HNCs in Kuwait (Morris, et al., 2000; Parikh and Ghamrawi, 1987) were conducted retrospectively, and therefore the aetiology could not be precisely defined. Nevertheless, some of the suggested risk factors relevant to Kuwait are genetic tendencies, endocrine status, diet, inhaled and occupational agents, viral infections, smoking and alcohol consumption.

2.1.3 Effects of head and neck cancer and its treatment on functional outcomes

As discussed in Chapter 1, HNC and its treatments, either single or multi-modality treatment lead to functional disorders (Schindler et al., 2019) such as speech difficulties, voice problems and dysphagia. Dysphagia is the most frequent acute and chronic complaint in HNC survivors (Jamal et al., 2017). Dysphagia may be under-reported in the clinical setting. Some patients may be unaware of the problem owing to a lack of laryngopharyngeal sensation and sub-clinical (silent) aspiration (Jamal et al., 2017) or believe that suffering and pain, in general, are inevitable with a cancer diagnosis (Wen and Gustafson, 2004). Another possible explanation for under-reported dysphagia is a lack of swallowing surveillance (Jamal et al., 2017).

Dysphagia may present before treatment and varies in type and severity following treatment depending on the modality. Unfortunately, it may remain a life-long issue for some HNC survivors (Patterson, Brady and Roe, 2016; Schindler et al., 2019). To the best of my knowledge, the prevalence of dysphagia in HNC patients in Kuwait has not been previously investigated. In the 12-year review conducted by Parekh and Ghamrawi in 1978, dysphagia and trismus were reported as baseline symptoms among other symptoms (sore throat, vertigo, toothache, paraplegia, backache and hoarseness) with a total prevalence of 25%. No specific prevalence was provided for dysphagia alone.

2.2 Rationale and study aim

Current HNC dysphagia data are required to facilitate better planning and allocation of health and rehabilitative services. Therefore, this study aimed to investigate the prevalence of HNC and dysphagia in Kuwait.

2.3 Methods

2.3.1 Ethical approval

Ethical approval was obtained from both Newcastle University (Ethics number: 1514_1/5577/2018; Appendix A), and Kuwait's Ministry of Health Research and Ethics Committee. A further approval was obtained from the KCCC management, to permit data extraction from the registry.

2.3.2 Data collection

This is a retrospective chart review and the data were collected from two sources:

1- The Cancer Registry located in the Kuwait Cancer Control Centre (KCCC).
2- Patient databases/files to gather missing information. As not all information is available on the registry, I had to request patients' files and conduct a chart review in order to retrieve the rest of the information.

Kuwait Cancer Registry

The Kuwait Cancer Registry (KCR) has systematically collected data of cancer cases in Kuwait since it was established in the radiotherapy department at Al-Sabah Hospital (a tertiary facility) in 1971. Its inaugural annual report was published in 1975, and in 1982 the KCR became a separate unit of the Kuwait Cancer Control Centre (KCCC; Kuwait Cancer Registry annual report, 2014).

All cancer patients are referred to the Kuwait Cancer Control Centre (KCCC), even if they are not initially diagnosed or treated there, for treatment and/or follow-up. The registry retains an index of information comprising case note number, names, sex, age, nationality, year of diagnosis and cancer site. All new registrations are checked against these indicators to avoid duplication (Kuwait Cancer Registry annual report, 2014)

Data on malignant neoplasms are collected according to the recommendations of the International Agency for Research on Cancer. All coding and data entry are completed by the registry staff of department of Epidemiology and Cancer Registry. The staff comprise: one epidemiologist, three tumour registrars, one computer technician and an assistant. The sources of information are case notes and pathology reports from the KCCC or other hospitals, along with mortality data taken from the Health Information Centre – Ministry of Health. Since January 1993 the registry has adopted ICD-O-2 and ICD-10. In August 2015 the registry transferred and adapted its codes to CanReg 5 and ICDO3. All data are documented manually, and then computerised by the registry staff (Kuwait Cancer Registry annual report, 2014).

2.3.3 Data retrieval

Registry data

An electronic search was conducted by the director of the KCR at my request to retrieve all cases of HNC diagnosed in the 6 years from 2009 to 2015. Initially, only cases from 2009 – 2013 were retrieved. However, this was later extended to include 2014 and 2015 data, as

more recent data became available. The inclusion criteria were adults aged 18 or older, new cancers diagnosed in the oral cavity, pharynx, larynx and sinuses. The core data was shared with me via an encrypted email, and patients' files were requested through the files section at the KCCC to extract the required information.

The data obtained from the registry were: cancer site, status i.e., alive or deceased and residential area. The rest of the data were obtained from patients' medical records. The initial variables I extracted were cancer site, TNM classification, treatment type, age, sex, marital status, ethnicity, education, alcohol and tobacco habits, and dysphagia and oral symptoms that contribute to swallowing problems (xerostomia, dysgeusia and trismus). I also noted the time course of symptoms and any SLT referrals undertaken. I later submitted an Ethics amendment (Newcastle: 1514_1/5577/2018) and obtained permission to collect data on HPV status for oropharyngeal cancer patients, area of residence and status as alive or deceased.

It should be noted that the data obtained from the registry and from patients' medical records were not prospectively recorded for the study, rather they were recorded as part of routine clinical practice.

Statistical analysis

I initially entered all data in Microsoft Excel and then uploaded into SPSS version 24 for statistical analysis. Descriptive statistics were obtained for all the variables, and for the three most common HNCs, in addition to dysphagia and the oral symptoms reported.

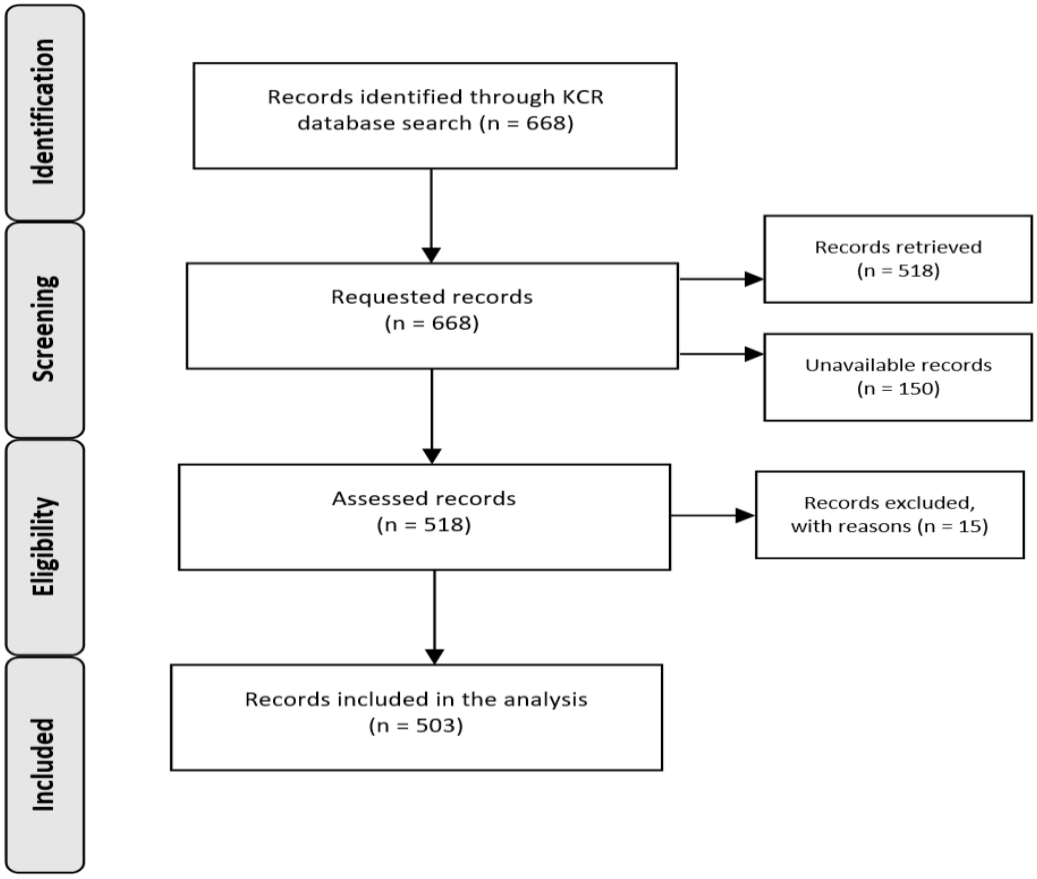
A cross-tabulation table was created to scrutinise the frequency of reported dysphagia and oral symptoms in different cancer sites. For the cross-tabulation analysis, cancers sites were grouped as: oral cancer, oropharyngeal cancer, NPC, laryngeal cancer (including cancers of the hypopharynx), and other HNCs. The latter group comprised ear/nose/sinus, parotid, head and neck lymphomas, lip, and cancers of unknown primaries. For analysis purposes, when patients report more than one symptom (e.g., dysphagia and trismus), they are reported as polysymptomatic. One-way ANOVA was used to test if there were significant differences based on age in different cancer groups (oral, oropharynx, nasopharynx, larynx, and other HNCs). Statistical significance was set at 0.05.

2.4 Results

2.4.1 Identification

In total, 668 new HNC cases were retrieved from the database from 2009 to 2015. Of all the requested files, only 459 files were retrieved initially, and 209 files were unavailable. Out of the 459 files, 12 were excluded. The 209 unavailable files were re-requested, and a further 59 files retrieved. Another three files were excluded. Therefore, there were 653 newly diagnosed adults with HNC, of which 503 (77%) were available. My analysis was therefore made on this convenience sample of n = 503 patients with HNC. Exclusions were: cancers in patients <18 years (n = 12), and cancers of other origins (n = 3), Figure 2.

Figure 2 Charts included in the analysis for HNC cases in Kuwait from 2009 to 2015



2.4.2 Demographics, tumour-related and clinical characteristics

The characteristics of my convenience sample of 503 patients diagnosed from 2009 to 2015 inclusive are given in Table 4. It is recorded that 95% of the sample were alive at the time of data collection. As ethnicity was not recorded, patients' nationality was obtained instead. Educational attainment was not available.

Table 4 Demographics, tumour-related and clinical characteristics of 503 HNC cases from 2009 – 2015

Variable	Category		Number (%)	Missing (%)
Age (years)	Range		18 - 87	5 (1)
	Median		52	
	Mean ± SD		53 ± 13	
Sex	Males		375 (75)	4 (1)
	Females		124 (25)	
Tumour site	Oral		179 (36)	-
	Larynx		114 (23)	
	Nasopharynx		95 (19)	
	Oropharynx		35 (7)	
	Ear/Nose/Sinus		20 (4)	
	Parotid		19 (4)	
	Head and neck lymphoma		16 (3)	
	Hypopharynx		12 (2)	
	Lip		7 (1)	
	Unknown primary		6 (1)	
Staging				
TNM	T	1	111 (23)	67 (14)
		2	113 (23)	
		3	65 (13)	
		4	125 (26)	
		x	6 (1)	
	N	0	202 (42)	66 (14)
		1	59 (12)	
		2	119 (24)	
		3	27 (6)	
		x	14 (3)	
	M	0	368 (76)	69 (14)
		1	18 (4)	
		x	32 (7)	
Ann Arbor (for lymphomas)	I	A	2 (13)	10 (63)
	II	A	1 (6)	
		B	1 (6)	
	III	A	1 (6)	
	IV	B	1 (6)	
Treatment	Chemoradiotherapy		158 (31)	50 (10)
	Surgery + (Chemo)radiotherapy		123 (25)	
	Surgery		96 (19)	
	Radiotherapy alone		72 (14)	
	Chemotherapy alone		3	
	Refused		1	

Table 4 Demographics, tumour-related and clinical characteristics of 503 HNC cancer cases from 2009 – 2015 *cont.*

Variable	Category	Results (%)	Missing values (%)
Origin (based on regions)	Middle-East	287 (57)	4 (1)
	Asia	183 (36)	
	Unspecified	13 (3)	
	Europe and North America	10 (2)	
	Africa	6 (1)	
Residency (governorate)	Hawally	136 (27)	11 (2)
	Farwaniya	123 (25)	
	Capital	81 (16)	
	Ahmadi	72 (14)	
	Jahra	50 (10)	
	Mubarak Al-Kabeer	30 (6)	
Marital status	Married/relationship	395 (79)	3 (1)
	Unspecified	52 (10)	
	Single	23 (5)	
	Widowed	18 (4)	
	Divorced	12 (2)	
Smoking status	No	167 (33)	126 (25)
	Yes	146 (29)	
	Ex	64 (13)	
Alcohol intake	No	223 (44)	243 (48)
	Yes	32 (6)	
	Ex	5 (1)	
Other habits	TBQ*	28 (6)	459 (91)
	Ex. TBQ	14 (3)	
	Ex. drugs	2	

**Tobacco, betel nut, and Qaat*

Table 5 and Figure 3 detail the geographic distribution of the country regions and residential areas based on governorates.

Tables 6, 7 and 8 and Figures 4 and 5 represent information extracted on oral cavity, larynx and nasopharynx cancers.

Table 5 Details of the specificities of the country regions, and residentials areas based on governorates.

Variable		
Region	Asia	Afghanistan, Bangladesh, India, Nepal, Pakistan, Sri-lanka, Indonesia, Philippines and Korea
	Africa	Kenya, Morocco, Somalia, Sudan and Tunisia
	Europe	Russia, Spain and UK
	North America	USA
	Middle East	Egypt, Iran, Iraq, Jordan, Kuwait, Lebanon, Palestine, Saudi Arabia, Syria, UAE and Yemen
Residency (based on governorate)	Ahmadi	11 districts, 5,120 km^2, population (2017): 959,009
	Capital	23 districts, 200 km^2, population (2017): 568,567
	Farwaniya	16 districts, 190 km^2, population (2017): 1,169,312
	Hawally	10 districts, 82 km^2, population (2017): 939,792
	Jahra	25 districts, 11,230 km^2, population (2017): 540,910
	Mubarak Al-Kabeer	8 districts, 100 km^2, population (2017): 254,999

Figure 3 Kuwait's governorates

Figure from: (Karageorgi, Alsmadi and Behbehani, 2013).

Table 6 Demographics and tumour-related characteristics of ***oral cancer*** patients in the study population (n = 179)

Variable	Category		Number (%)	Missing (%)
Age (years)	Range		(24 – 87)	-
	Median		51	
	Mean ± SD		52 ± 14	
	≤ 45 years		61 (34)	
Sex	Males		123 (69)	-
	Females		56 (31)	
Staging				
TNM	T	1	42 (24)	30 (17)
		2	43 (24)	
		3	12 (7)	
		4	52 (29)	
	N	0	75 (42)	29 (16)
		1	26 (15)	
		2	38 (21)	
		3	3 (2)	
		x	8 (5)	
	M	0	136 (76)	31 (17)
		1	4 (2)	
		x	8 (5)	
Treatment	Surgery		71 (40)	15 (8)
	Surgery + (Chemo)radiotherapy		70 (39)	
	Chemoradiotherapy		16 (9)	
	Radiotherapy		4 (2)	
	Chemotherapy		2 (1)	
	Refused		1 (1)	
Smoking status	No		69 (39)	55 (31)
	Yes		40 (22)	
	Ex		15 (8)	
Alcohol intake	No		73 (41)	89 (50)
	Yes		16 (9)	
	Ex		1	
Other habits	TBQ*		19 (11)	149 (83)
	Ex. TBQ		11 (6)	

**Tobacco, betel nut, and Qaat*

Table 7 Demographics and tumour-related characteristics of ***laryngeal cancer*** patients n = 114

Variable	Category		Number (%)	Missing (%)
Age (years)	Range		(29 – 84)	2 (2)
	Median		57	
	Mean ± SD		57 ± 12	
	≤ 45 years		19 (17)	
Sex	Males		102 (90)	1 (1)
	Females		11 (10)	
Staging				
TNM	T	1	35 (31)	6 (5)
		2	29 (25)	
		3	26 (23)	
		4	18 (16)	
	N	0	83 (73)	6 (5)
		1	9 (8)	
		2	12 (11)	
		3	1 (1)	
		x	3 (3)	
	M	0	102 (90)	6 (5)
		1	1 (1)	
		x	5 (4)	
Treatment	Radiotherapy		54 (47)	8 (7)
	Surgery + (Chemo)radiotherapy		22 (19)	
	Chemoradiotherapy		22 (19)	
	Surgery		8 (7)	
Smoking status	No		18 (16)	12 (11)
	Yes		57 (50)	
	Ex		27 (24)	
Alcohol intake	No		58 (51)	49 (43)
	Yes		6 (5)	
	Ex		1 (1)	
Other habits	TBQ*		1 (1)	112 (98)
	Ex. TBQ		1 (1)	

**Tobacco, betel nut, and Qaat*

Table 8 Demographics and tumour-related characteristics of ***nasopharyngeal cancer*** patients n =95

Variable	Category		Number (%)	Missing (%)
Age (years)	Range		(18 – 74)	-
	Median		48	
	Mean ± SD		48 ± 13	
	≤ 45 years		40 (42)	
Sex	Males		68 (72)	-
	Females		27 (28)	
Staging				
TNM	T	1	24 (25)	9 (10)
		2	18 (19)	
		3	18 (19)	
		4	26 (27)	
	N	0	11 (12)	9 (10)
		1	16 (17)	
		2	44 (46)	
		3	15 (16)	
	M	0	74 (78)	10 (11)
		1	9 (10)	
		x	2 (2)	
Treatment	Chemoradiotherapy		80 (84)	7 (7)
	Radiotherapy		7 (7)	
	Chemotherapy		1 (1)	
Smoking status	No		38 (40)	21 (22)
	Yes		26 (27)	
	Ex		10 (11)	
Alcohol intake	No		47 (50)	44 (46)
	Yes		4 (4)	
Other habits	TBQ*		2 (2)	93 (98)

**Tobacco, betel nut, and Qaat*

Figure 4 Origin (based on regions) for oral, laryngeal and nasopharyngeal cancer patients

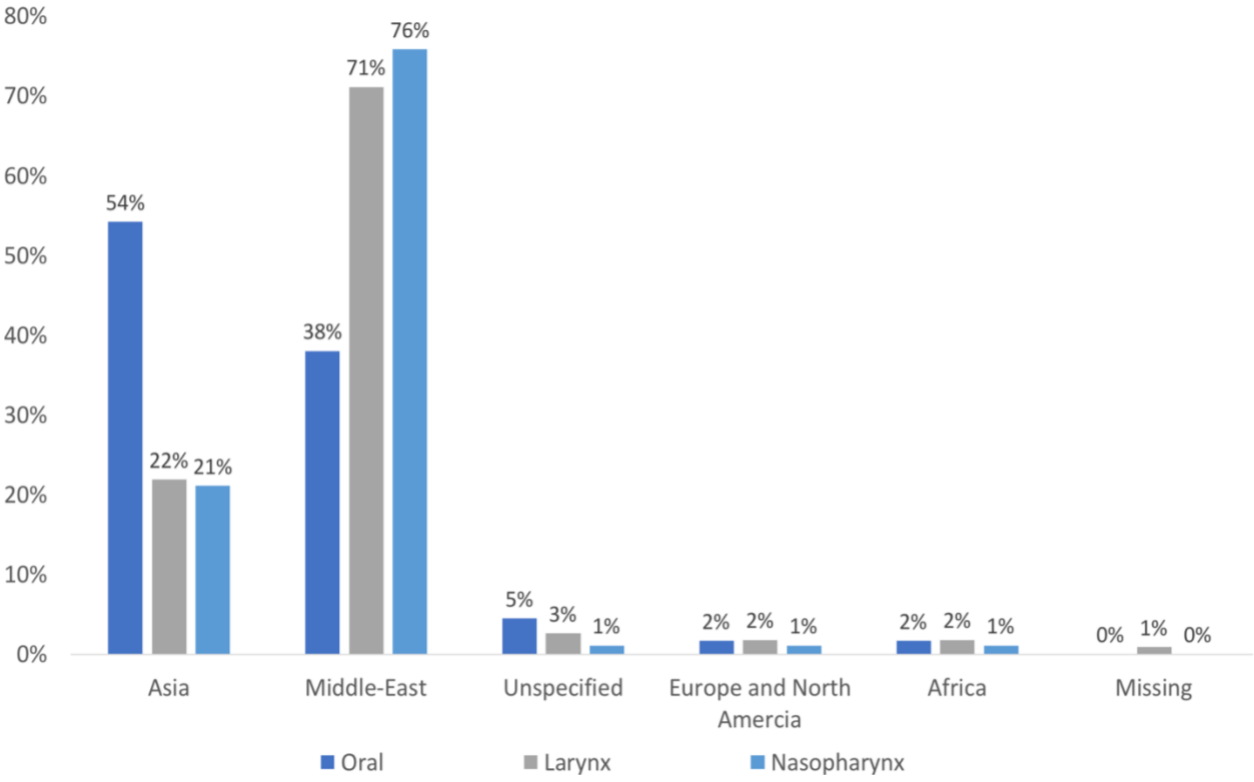
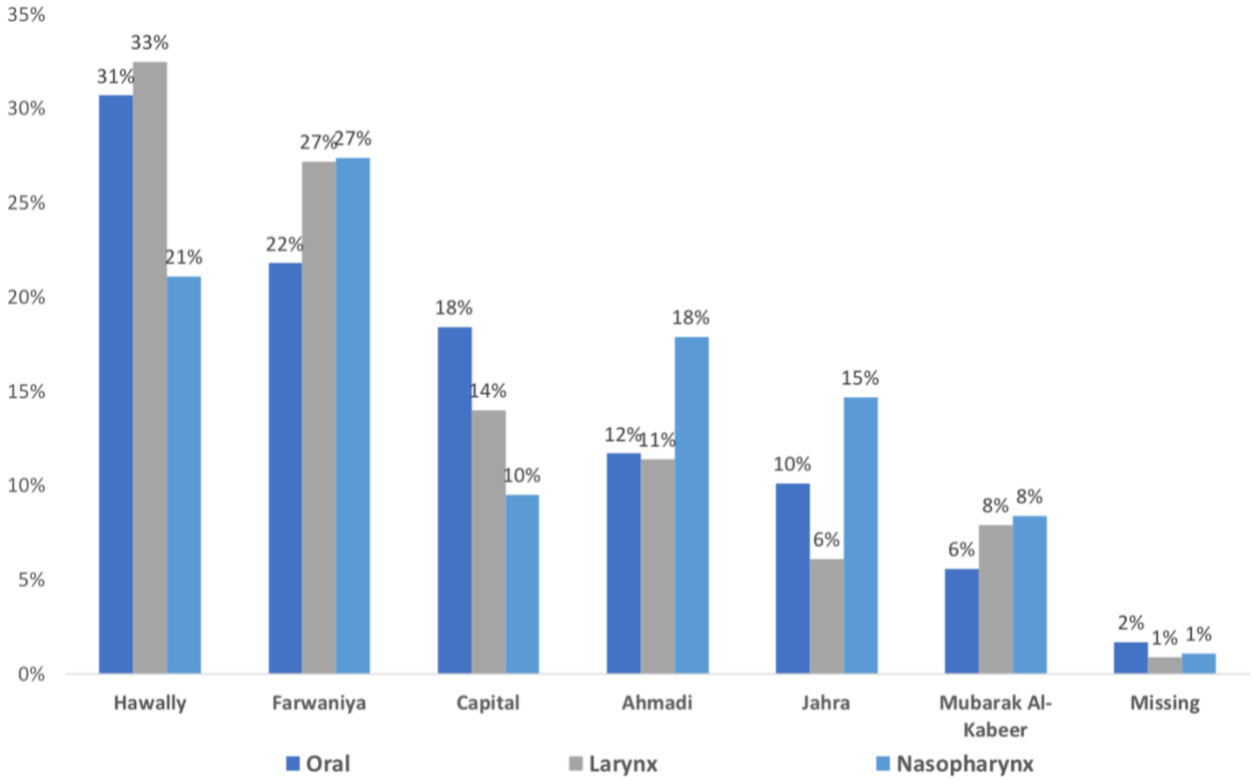


Figure 5 Residency based on governorate for oral, laryngeal and nasopharyngeal cancer patients



Differences between tumour sites based on patients' age

There was a statistically significant difference in age between different tumour sites, *F (4, 493) = 6.73, p < 0.000*. The significant difference in age was observed between oral and laryngeal cancer; mean difference -5 years (*p = 0.016*), nasopharynx and laryngeal cancer; mean difference -9 years (*p < 0.000*), and between other HNCs and laryngeal cancer; mean difference -6 years (*p =.031*). Tables 9 and 10.

Table 9 Mean age of different cancer sites in HNC patients diagnosed from 2009 – 2015

Cancer site	n	Mean ± SD	Confidence interval (95%)	Min-Max
Oral	179	52 ± 14	50, 54	24 – 87
Oropharynx	35	55 ± 12	51, 59	35 – 86
Nasopharynx	95	48 ± 13	45, 51	18 – 74
Larynx	124	57 ± 12	55, 59	29 – 84
Other HNCs	65	51 ± 14	48, 55	26 – 85
Total	498	53 ± 13	51, 54	18 - 87

Other HNCs: ear/nose/sinus, parotid, head and neck lymphomas, lip, and cancers of unknown primaries

Table 10 Multiple group comparisons for age between the cancer site in HNC patients diagnosed from 2009 – 2015, using the post-hoc Tukey HSD

Cancer site (I)	Cancer site (J)	Mean age difference (I-J)	Standard error	Sig.	Confidence interval (95%)
Oral	Oropharynx	-3	2	0.794	-9, 4
	Nasopharynx	4	2	0.106	-0.5, 9
	Larynx	-5*	2	0.016	-9, -0.6
	Other HNCs	1	2	0.982	-4, 6
Oropharynx	Oral	3	2	0.794	-4, 9
	Nasopharynx	7	3	0.069	-0.3, 14
	Larynx	-2	3	0.924	-9, 5
	Other HNCs	4	3	0.647	-4, 11
Nasopharynx	Oral	-4	2	0.106	-9, 0.5
	Oropharynx	-7	3	0.069	-14, 0.3
	Larynx	-9*	2	0.000	-14, -4
	Other HNCs	-3	2	0.608	-9, 3
Larynx	Oral	5*	2	0.016	0.6, 9
	Oropharynx	2	3	0.924	-5, 9
	Nasopharynx	9*	2	0.000	4, 14
	Other HNCs	6*	2	0.031	0.3, 11
Other HNCs	Oral	-1	2	0.982	-6, 4
	Oropharynx	-4	3	0.647	-11, 4
	Nasopharynx	3	2	0.608	-3, 9
	Larynx	-6*	2	0.031	-11, -0.3

Other HNCs: ear/nose/sinus, parotid, head and neck lymphomas, lip, and cancers of unknown primaries

2.4.3 Dysphagia and oral symptoms

Dysphagia and oral symptoms were reported using the National Cancer Institute – Common Terminology Criteria for Adverse Events (NCI-CTCAE). How dysphagia, and oral symptoms were defined or described to/ and by the patients is unknown. Furthermore, it is also unknown if these symptoms were reported by the patients, or enquired by the treating oncologist.

Based on the available data from patients files, these symptoms were documented in 225 of the 503 patient files (45%), at least at one time point of their treatment journey (total n = 225). Only 1% (n = 5) denied any symptoms. The information is summarised in Table 11.

Table 11 Dysphagia and oral symptoms as reported by using the NCI-CTCAE (n = 503)

Variable	Frequency	Percentage
Dysphagia	121	24%
Polysymptomatic	64	13%
Xerostomia	34	7%
Trismus	5	1%
No symptoms	5	1%
Senses	1	-
Total reporting symptoms	225	45%
Total denying symptoms	5	1%
No information	273	54%
Total HNCs	503	100%

Polysymptomatic (e.g., dysphagia and trismus)

The majority of patients reporting dysphagia were laryngeal (20%) and oral (15%) cancer patients. Moreover, 28% of the 230 patients reported more than one symptom at a time, with 12% of the 28% being patients with NPC. Table 12, Figures 6 and 7 provide more details of symptoms reported based on specific tumour sites for 230 patients who had available information.

Table 12 Dysphagia and oral symptoms as reported by patients with different tumour site n = 230 patients **and recorded using the NCI-CTCAE**

Cancer site		Symptom						Total
		Xerostomia	Trismus	Dysphagia	Senses	Polysymptomatic	Nil	
Oral	n	7	4	34	0	16	2	63
	% within	11%	6	54%	0	25%	3	100%
	% of total	3	2	15%	0	7	1	27%
Oropharynx	n	2	0	15	0	9	0	26
	% within	8	0	58%	0	35%	0	100%
	% of total	1	0	7	0	4	0	11%
Nasopharynx	n	18	0	18	0	27	0	63
	% within	29%	0	29%	0	43%	0	100%
	% of total	8	0	8	0	12%	0	27%
Larynx	n	6	0	47	1	9	2	65
	% within	9	0	72%	2	14%	3	100%
	% of total	3	0	20%	0	4	1	28%
Other HNCs	n	1	1	7	0	3	1	13
	% within	8	8	54%	0	23%	8	100%
	% of total	0	0%	3	0	1	0	6
Total	n	34	5	121	1	64	5	230
	% of total	15%	2%	53%	0	28%	2	100%

The '%within' compares the symptoms within the tumour site (e.g. % of patients reporting dysphagia vs. % of patients reporting xerostomia within oral cancer), whereas '%of total' compares the data between all tumour sites (e.g. % of patients reporting dysphagia in oral cancer vs. % of patients reporting dysphagia in laryngeal cancer

Figure 6 Dysphagia and oral symptoms by HNC site (percentages represent the prevalence ***within*** each tumour site n = 230)

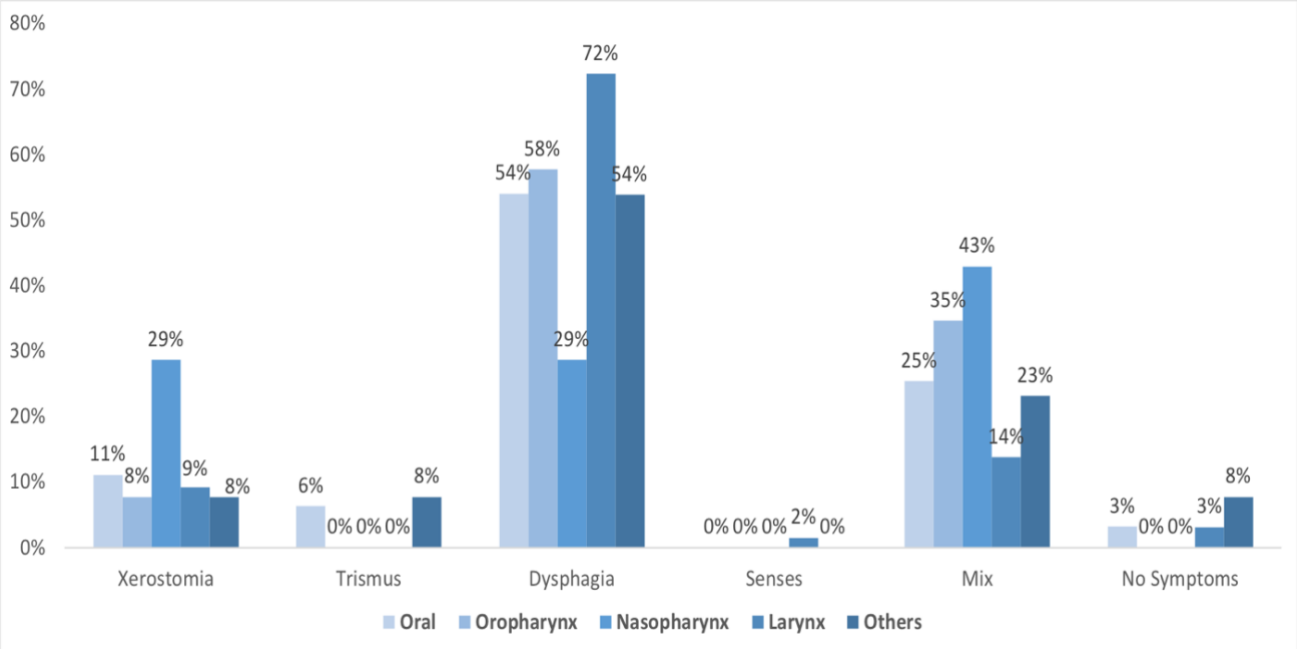
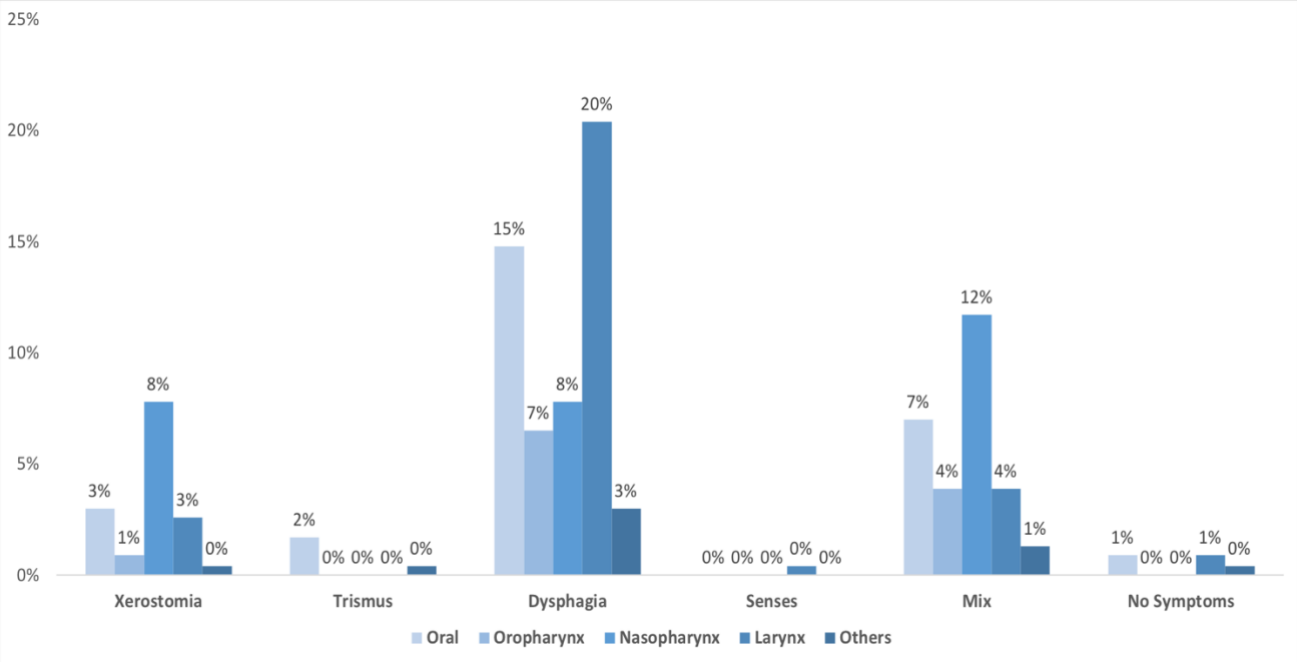


Figure 7 Dysphagia and oral symptoms as reported by HNC site (percentages represent the prevalence ***between*** all HNCs n = 230)



2.5 Discussion

This study aimed to investigate the prevalence of HNC and dysphagia in Kuwait. To the best of my knowledge, it is the first to report on all HNCs – including laryngeal cancer – in Kuwait in 21 years and the first to report on dysphagia in HNC patients. The data were obtained from a convenience sample of 503 patients between 2009 and 2015. The three most prevalent sites of cancer in the head and neck region are oral cavity (36%), larynx (23%) and nasopharynx (19%). Dysphagia, a common consequence of the disease, was documented by 45% of patients at different time points. Understanding the prevalence of a disease allows for proper healthcare planning, in terms of awareness, care setting and management.

2.5.1 General remarks

Selection bias

It would have been more ideal to retrieve all tumour-related characteristics from the KCR; however, the only information obtained from the KCR was related to tumour site, patients' status, year of diagnosis, and residency area. The number of missing files in the present study was high (23%) (see section 2.4.1), these files may not be technically missing, rather unavailable either due to discontinued follow-up or patient death. Overall, 95% of the 503 patients were considered to be alive at the time of the present study (2018 – 2019) (i.e., 4 – 9 years post diagnosis). In general, the five-year survival rate for HNC varies depending on several factors including tumour site and stage (discussed in Chapter 1), however it is around 29-82% (Louie et al., 2015; Petersen et al., 2018; Chapter 1). In the UK, the 5-year survival rate is between 28 – 67% whereas the 10-year survival being between 19 – 59% (Cancer Research UK, D.A, 2021). The 95% reported in the current study may not be reflective of true numbers and may be an artefact of patient loss to follow-up because over 70% of the population of Kuwait are expatriates, in addition to many people seeking treatment, or follow-up abroad. In a study by Morris et al. (2000), more than 25% of the patients were lost to follow-up after five years. The loss to follow-up was not investigated in the present study.

Reporting bias

Alcohol and some other behaviours (e.g., betel nut chewing) are prohibited in Kuwait. This may impede reporting of their use, these two variables are important as they are highly

linked to HNC development, prognosis, and severity of dysphagia. Furthermore, there was a large number of information missing from the files (e.g., TNM staging (14%), treatment type (10%)), this may be linked to a high proportion of patients who travel abroad to seek medical treatment, and many of them do not have their medical reports or provide minimal information regarding their medical status and the care received.

2.5.2 Oral cancer

Oral cancer was the leading HNC (36%) in the present study. Smoking and tobacco chewing are highly associated with oral cancer, and these habits were identified in 22% and 11% of the patients, respectively. In Arab countries, oral cancer represents 2–18% of all cancers and up to 59% of HNCs (Al-jaber, Al-nasser and El-metwally, 2016), with a significant proportion of patients (15%) being younger than 45 years (Hussein et al., 2017). In the present study, 34% (n = 61/179) of oral cancer patients were 45 years old or younger. Previously, it has been reported that 34% of oral cancer patients in Kuwait were diagnosed before the age of 40 (Morris, et al., 2000). This is substantially younger than most published papers where the mean age of oral cancer is 62 years (Sarode et al., 2020; Warnakulasuriya and Greenspan, 2020). A systematic review on oral cancer in young people reported that there in a general worldwide increase in the rate of oral cancer in younger people.The highest rates were from Asia (12%) and the Middle East (15%) in comparison with for example Europe (7%) and the USA (5%; Hussein et al., 2017). The authors suggest that poor oral diet, and habits of using tobacco, and possibly the reluctance of older people to seek help should they show any symptoms (Hussein et al., 2017; Warnakulasuriya and Greenspan, 2020). Further studies are required to fully understand the extend of the problem and to explore the possibility of involvement of other risk factors (Hussein et al., 2017; Paderno, Morello and Piazza, 2018).

Oral cancer is a visible lesion and can be detected during a routine follow-up visit with the dentist. In Kuwait, primary care centres provide dental and oral health services for all patients in the six governorates. Nearly all the dentists in the six governorates (99.7%) demonstrated awareness of the major risk factors of oral cancer; however, only 32% of them reviewed these risk factors, with 62% assessing for tobacco use only. Moreover, only 31% of the dentists were aware of the symptoms of early stages of oral cancer (Nazar et al., 2019). This lack of awareness could delay the identification of these lesions and

consequently delay oral cancer diagnosis, especially considering that most dental visits are driven by pain (Alkhubaizi et al., 2018)

In a study investigating the public awareness of oral cancer risk factors in Kuwait, two-thirds of participants identified tobacco smoking and chewing and alcohol consumption as risk factors. The knowledge of oral cancer signs and symptoms was poor; only fewer than four in 10 participants were aware that non-healing mouth ulcers and neck lumps may be signs of oral cancer (Joseph, Ali, and Sundarm, 2018). However, the participants were all recruited from a single dental treatment centre. In another study, aiming to investigate the prevalence of oral cancer screening among smokers and non-smokers in Kuwait, oral cancer screening was lacking even in smokers. As an outcome of that work, an oral screening campaign was conducted in a shopping mall in Kuwait, resulting in more than 700 oral screens being provided to the public (Alkhubaizi et al., 2018). Unfortunately, the results of the screening campaign were not reported. Given the diverse nature of the population of Kuwait where 70% of the population are expatriates, an important limitation of the above study was that it did not include the expatriate communities as the survey targeted Kuwaiti nationals only. Targeting diverse populations in public health campaigns should be considered, especially because the findings of the present study suggest that HNC patients are of different origins, and predominantly are from Asia. Similar campaigns conducted in Oman from 2015 to 2019 resulted in 509 HNC screens; only 6% of these required further evaluation for suspected lesions, with no confirmed malignant findings (Al-Dhahli et al., 2020). The Oral, Head and Neck Cancer Awareness (OHANCA) programme led by the Head and Neck Cancer Alliance in the United States hosts an annual free screening for the public in the united states and different counties (https://www.headandneck.org/ohancaw/). Such campaigns are important as they spread awareness, encourage screening which may facilitate early detection in order to improve outcomes.

2.5.3 Laryngeal cancer

Despite the steady increase in tobacco smoking – a known major risk factor for laryngeal cancer – in the GCC countries including Kuwait (Al-Zalabani, 2020), the current study is the first study, to my knowledge, to report on the prevalence of laryngeal cancer in Kuwait. Laryngeal cancer was the second most common HNC, accounting for 23% of all HNCs in Kuwait. Smoking was reported by 74% of laryngeal cancer patients, with 24% of them being

ex-smokers, whereas 6% of the patients reported alcohol consumption. Although laryngeal cancer risk declines with the increase in years of smoking cessation, unfortunately, it is not the case for heavy smokers. A study reported that 54% and 7% of young male adults in Kuwait are considered moderate smokers (1-2 packs per day) and heavy smokers (>3 packs per day), respectively, and 63% started smoking at a young age (13–19 years; Husain et al., 2016).

Regionally, laryngeal cancer was reported to be the eighth most common cancer in Bahrain (Alhilli and Das, 2010). In Yemen, laryngeal cancer was the third most common cancer between HNCs, its rank amongst all cancer site was not reported (Abdul-hamid et al., 2010). In both these countries, smoking rates are high. Worldwide, the incidence of laryngeal cancer is declining with the decline in tobacco use (McDermott and Bowles, 2019). On average, laryngeal cancer rates have been declining by 2% each year for the past decade in the United States of America (USA; SEER, 2020). In the United Kingdom (UK), laryngeal cancer is the most common HNC site in males (26%), and in females, it accounts for 13% of HNCs; Cancer Research, UK, D.A: 2020).

2.5.4 Nasopharyngeal cancer

In an early Kuwait study, NPC was the commonest HNC site (Parikh and Ghamrawi, 1978) and continued to be the leading HNC years later (Morris et al., 2000). In the present study, NPC was still found to be very common; however, its prevalence has been surpassed by that of oral and laryngeal cancers. Worldwide, NPC is considered as a rare cancer, mostly common in Asia, and its incidence has been declining over the past decade (Ramsey et al., 2019). This decline is believed to be linked to increased public awareness and changes in dietary habits (Chang and Hildesheim, 2017). The reason behind the NPC decline in Kuwait remain speculative, as there have been no relevant aetiological studies. NPC is common in Saudi Arabia, where it represents 33% of all HNC diagnoses (Alotaibi, Ahmed and Elasbali, 2019), whereas in Oman, it appears much be less common, with only 26 reported cases in the main tertiary hospital of head and neck surgery between 2003 and 2011 (Al-Azri and Al-Sheibani, 2015). NPC is commonly associated with Epstein–Barr virus (EBV) infection, environmental and host factors and, as reported more recently, HPV infection (Chang and Hildesheim, 2017; Devins et al., 2019; Lee et al., 2009; Warnakulasuriya and Greenspan, 2020; discussed in Chapter 1).

Worldwide, approximately 80% of NPC cases are found in Asia (Chen et al., 2021; Mahdavifar et al., 2016). In the present study, 76% of NPC patients were from the Middle East and only 21% were found to be from Asia. This disparity warrants further prospective studies to identify the risk factors associated with NPC in Kuwait and in the Middle East.

2.5.5 Oropharyngeal cancer

Although oropharyngeal cancer is not common in Kuwait, a comparison with the global statistics is warranted because while the incidence of all other HNCs is declining, that of oropharyngeal cancer is increasing, especially in Europe, North America and Australia. This increase is attributed to the rapid increase in HPV infections (Louie et al., 2015). In the present study, the 35 oropharyngeal cancers in Kuwait between 2009 and 2015 accounted for 7% of all HNCs. The HPV status of these oropharyngeal cancer patients was unavailable. It is important to identify HPV-associated oropharyngeal cancer as it responds differently to treatment and requires more personalised treatment than HPV-negative oropharyngeal cancer (Alsbeih et al., 2019; Menezes et al., 2021; Petar, Marko and Ivica, 2021). It has been suggested that by 2030, the majority of HNCs in the USA will be HPV related (Chaturvedi et al., 2011). However, it should be noted that there is a geographic disparity in HPV prevalence; (Chapter 1; section 1.2.2). A pooled analysis confirms a prevalence of 59% and 31% HPV-positive oropharyngeal cancer in the USA and Europe, respectively (Anantharaman et al., 2017) whereas in Saudi Arabia, a neighbouring country of Kuwait, the prevalence of HPV-positive oropharyngeal cancer accounted for 21% of all oropharyngeal cancer cases (Alsbeih et al., 2019). The prevalence of HPV-associated oropharyngeal cancer in Kuwait remains unknown and, to my knowledge, has not been investigated on a population level.

2.5.6 Prevalence of dysphagia and oral symptoms

In the present study, dysphagia was recorded using the NCI-CTCAE version 4 scale (NCI, 2010). This clinician-graded tool was developed by the National Cancer Institute (USA) to document toxicities during and following cancer treatment. Dysphagia, trismus, xerostomia, and dysgeusia are all included in this scale, and the grade ranges from 1 to 5 (depending on the symptom). The lower the grade, the milder the symptom is. Although this tool is widely used and reported upon, it does not capture all the outcomes concerning swallowing impairment, such as the pathophysiology of swallowing and impact on quality of life. In this scale, impairments are limited to dietary restrictions and method of oral

intake (Hutcheson et al., 2017). Therefore, it may not be a sensitive metric to capture swallowing dysfunction. Moreover, the reliability and validity of this tool for these symptoms and its sensitivity to changes over time have not been described. Reliability and validity and sensitivity to change are desirable when assessing a vulnerable group that is prone to variations in functioning during treatment and for many years subsequently. Thus, the NCI-CTCAE should not substitute a comprehensive multidimensional assessment offered by an expert speech and language therapist (SLT; discussed in more detail in Chapter 1).

In Chapter 1, I discussed swallowing impairments in HNC patients at baseline, during and following treatment. In this study, dysphagia and oral symptoms were reported by almost half of the convenience sample of HNC patients (45%) at least at one time point. It is expected that this may be an underestimation of the true prevalence for different reasons. It has been described elsewhere that around 30 – 52% of patients with HNC have pre-treatment dysphagia (Kristensen et al., 2020; Platteaux et al., 2010), and a conservative estimate of dysphagia post-(C)RT is around 60% (Shune et al., 2012). Additionally, a study reporting on the two-year prevalence of dysphagia post treatment estimated that about 45% of survivors have dysphagia (Hutcheson et al., 2018).

As mentioned earlier in this section, the tool (NCI-CTCAE version 4) used to report on dysphagia and oral symptoms is a clinician-graded tool and does not effectively capture the type of dysfunction. Moreover, it has been suggested that acute toxicities (including dysphagia) are often underestimated and unrecognised - hence under reported –by both patients and physicians (Kearney and Cavanagh, 2019; Shune et al., 2012). There are several reasons for patients under-reporting their symptoms; for example, some patients may be unaware of their swallowing difficulties owing to reduced oral and laryngeal sensation as a result of treatment (Starmer, 2019). Furthermore, as stated earlier, some patients believe that difficulties associated with cancer treatment are expected and unavoidable with a cancer diagnosis, or patients may not report expected adverse outcomes from anticancer treatments (Di Maio et al., 2015; Wen and Gustafson, 2004). Qualitative studies exploring the experience of living with eating and drinking difficulties in HNC patients report ‘the downplaying phenomenon’, first portrayed by Wells (1998), where cancer patients believe that the functional and physical difficulties are ‘the price to be paid for survival’ (Crowder, et al., 2021; Ottosson, Laurell and Olsson, 2013; Wells,

1998). This phenomenon poses a risk of under-exploration of these symptoms (Einarsson, Laurell and Ehrsson, 2018) and consequently under-reporting of these symptoms and increased morbidity. It is also evident from the literature that some patients often choose to continue oral feeding despite evidence of dysphagia or aspiration (Hutcheson et al., 2017); therefore, the NCI-CTCAE may not be the optimal tool for assessing dysphagia and should not substitute a comprehensive swallowing assessment.

Studies about other cancer sites found that there is a poor agreement between patient-reported and clinician-reported toxicities during cancer treatment (Di Maio et al., 2015; Veitch et al., 2021). For example, a study aimed to establish agreement between patients and physician reporting of adverse events in three trials by comparing the results of the NCI-CTCAE version 3, with a cancer-specific quality of life questionnaire, found that there is a disagreement and a high rate of underreporting of subjective treatment toxicities (anorexia, nausea, vomiting, constipation, diarrhoea and hair loss) between doctors and patients (Di Maio et al., 2015). This lack of agreement for subjective symptoms was also described elsewhere (Basch et al., 2006). As these symptoms are only apparent and felt by the patients, their report, and described severity should be taken into account.

Considering the extensive risk of underreporting dysphagia using one method of assessment, incorporating a multi-dimensional assessment within the practice is important. Later in the thesis, I will be describing the development of a prototype for a Swallowing Outcomes Package as one of the key outcomes of the thesis. The proposed package can be easily integrated in the clinical practice, which may enhance the discovery and reporting of dysphagia.

2.6 Limitations

A retrospective chart review such as I have described above has advantages of exploiting available data sources at a low cost. However, this method also has some limitations, for example, missing charts and incomplete documentation (Gearing et al., 2006). As the data obtained from the charts were not recorded specifically for the purpose of this research, not all variables were available for each patient. In addition, there was a large number of inaccessible/unavailable files possibly owing to loss of follow-up or death (23%). As a consequence, the results reported may not represent the true values and may be an underrepresentation of the actual prevalence or an overestimation if all the case notes that

I did not have access to show no dysphagia. In the present study, no imputation techniques were applied to manage missing data.

2.7 Clinical implications

The current study offers the most recent statistics on HNCs and an estimate of dysphagia prevalence in HNC patients in Kuwait, thus facilitating a preliminary understanding of the problem and better allocation of health and rehabilitative services. The results of this study suggest that the three most common HNCs in Kuwait are oral, laryngeal, and NPCs. HNCs are relatively preventable by avoiding or reducing exposure to risk factors. The findings of this study can be used to inform public health campaigns about the importance of smoking cessation and health hazards of increased alcohol consumption, betel nut chewing and similar behaviours. While several campaigns have taken place, they mainly targeted specific populations (e.g., students). Future campaigns should be directed at diverse populations, since the results from the current study suggest that the HNC patient population is diverse. Moreover, resources should be created for and made easily accessible to individuals who wish to stop smoking. Members of the public should also have access to information about the risks of increased alcohol consumption, highlighting the resources and routes available to them for assistance if they wish to confidentially discuss their drinking situations with a healthcare professional, since alcohol consumption is prohibited in Kuwait.

Moreover, as oral cancer can be visually inspected, it is important to inform the public about the oral screening methods and the importance of early detection by recognising the signs and symptoms of oral cancer. It is well established that early detection and diagnosis of HNC is key for improved patient outcomes (Nieminen et al., 2021). As the results of this study suggest, and in accordance with the prevalence of oral cancer amongst Asians, it is important to identify individuals who are at high risk of developing oral cancer in order to facilitate follow-ups and oral screenings. Simple, short, and informative videos or educational resources can be produced to educate individuals on how to easily perform self-examinations (e.g., the Mouth Cancer Foundation: www.mouthcancerfoundation.org and the European Head and Neck Society www.makesensecampaign.eu website). Such resources can be easily distributed and accessed, and they can provide simple and visual information to the public. Additionally, because the global prevalence of oropharyngeal cancer is increasing, it is important to consider vaccination campaigns for both sexes.

The results of this study also provide evidence for the need of a dysphagia clinic setup to appropriately identify, assess and manage swallowing problems in HNCs, to reduce dysphagia burden, and improve quality of life.

2.8 Implications for future research

The results of this study can inform future prospective studies that aim to investigate HNC and dysphagia prevalence in Kuwait. Future studies aiming to estimate HNC and dysphagia prevalence should focus on prospectively collected data using appropriate dysphagia assessment methods to gain a better understanding of the true incidence. This clinical project can be led by head and neck cancer teams.

Future epidemiological studies should be performed to identify the aetiology of HNCs in Kuwait, in order to appropriately plan services for this cancer. Moreover, it is important to identify any disparities in care amongst the population in Kuwait in order to facilitate and improve survivorship experience. Furthermore, routine measurement of HPV status in HNC patients also requires attention.

Chapter 3: Experiences and unmet needs of head and neck cancer patients in Kuwait

In the previous chapter, I reported on the prevalence of HNC and dysphagia in Kuwait. The results indicated that oral, laryngeal and nasopharyngeal cancers (NPC) are in the top three HNCs. The results also could possibly indicate that dysphagia, which contributes to increased morbidity and decreased quality of life, is an underreported symptom. Patients living with dysphagia may have specific care needs. This chapter reports the results of a qualitative study that explored the unmet needs of HNC patients in Kuwait. It should be noted that the patients recruited in this study are not part of the previously discussed study in chapter 2.

3.1 Literature Review

The advance in treatment coupled with changes in the aetiology of HNC have resulted in enhanced survival outcomes (Song et al., 2020; Zevallous and Kramer, 2020). Unfortunately, HNC survivorship is often accompanied by devastating sequelae of treatment, even years after treatment termination (Jensen et al., 2020; Mezi et al., 2020; Szturz et al., 2018; Taberna et al., 2015; Wang et al., 2019). It is important to understand patients' needs and requirements so that resources and services can be prioritised in a way that achieves the best care and well-being outcomes for patients. For a complex group such as HNC, patients' needs are often multifaceted due to the nature and complexity of both the disease and its treatment (Mayland, et al., 2020). Many HNC studies rely on questionnaires to capture overall needs (e.g., psychological, physical, health system and informational) (Chen et al., 2012; Jansen et al., 2018) or one aspect of needs (e.g., informational needs (Chen et al., 2009). The most common HNC-specific needs typically concern difficulties with chewing, eating, drinking and a dry mouth (Jansen et al., 2018; Wells et al., 2015). Between 38% and 42% of HNC patients require services from Speech and Language Therapists (SLTs) and express interest in resources to help with swallowing difficulties (Giuliani et al., 2016; Henry et al., 2014; Oskam et al., 2013). This evidence base emanates predominantly from the United Kingdom (UK), the Netherlands, Canada and Australia; however, HNC patients' needs have not been previously investigated in Kuwait.

Having dysphagia and oral symptoms can potentially affect patients physically and psychologically, hindering their participation in social activities and compromising their quality of life (QOL). HNC patients who experience dysphagia after non-surgical treatment often report that they are unprepared for dealing with this side-effect, and they express the need for ongoing support services to assist with eating (Nund et al., 2014). This need was also highlighted in a systematic review looking at the life experience of the impact of nutrition symptoms (e.g., dysphagia and xerostomia) on HNC patients (Bressan et al., 2017).

A needs assessment allows healthcare providers to identify patients who require high-level support and to implement timely preventive measures (Bonevski et al., 2000; Boyes, Girgis, D'Este and Zucca, 2012; Rafie et al., 2019). The lack of information on HNC patients' needs regarding dysphagia and oral symptoms in Kuwait is an obstacle to the development of patient-centred care and pre-habilitative and rehabilitative services. Tackling these functional impairments is challenging, as swallowing is multifactorial; therefore, identifying patients' needs is essential to improve and provide these services.

3.2 Rationale, study aim and objectives

As the majority of the literature describing dysphagia experiences and unmet needs emerges from western contexts, e.g., the United States, Europe and Australia, it is important to understand the experience of symptoms as lived by patients in Kuwait, because symptoms are a social construct, i.e., they change across different cultures and contexts (Graffigna et al., 2011). Moreover, understanding patients' needs appears to be a reasonable first step in the effort to reduce morbidity and improve QOL (Nguyen and Ringash, 2018; Rajah et al*.,* 2021).

This study aims to highlight the unmet dysphagia needs of HNC patients in Kuwait.

Objectives:

1- Understand the nature and experience of swallowing difficulties.
2- Explore patients' experiences with dysphagia management.
3- Identify patients' needs regarding dysphagia services.

3.3 Methods

3.3.1 Ethical approval

Ethical approval was obtained from both Newcastle University and Kuwait's Ministry of Health Research and Ethics Committee. Ethics application number 1517/5666/2018. Appendix B.

3.3.2 Study design

A qualitative study design was selected in this study in order to gain a broader understanding of the issues faced by HNC patients in Kuwait. To my knowledge this is the first opportunity for this patient population to articulate their experiences.

3.3.3 Data collection

An interview design was adopted rather than online or paper surveys to fully understand the complexity and nature of patients' experiences and needs. Although a questionnaire survey may be applied to larger numbers of participants, it may also risk losing in-depth meanings and experiences.

The one-to-one interview method allowed exploration and hence more meaningful understanding of a multi-dimensional topic such as swallowing impairment with all its biopsychosocial implications. In addition, interviews allow the appreciation of the unique journey of the patients, and of their lived experiences in dealing with these side-effects, particularly given that there are few pre-existing support services. Although focus groups would have facilitated discussions and group interactions (Patterson and Dawson, 2017), these were not set up for this study for several reasons. Firstly, the discussions may have included some sensitive details about the experience of swallowing difficulties and their impact on the physical, emotional, and functional aspects of life, and a group setting might have inhibited the participants from sharing these experiences. Moreover, there were some very personal questions about the impact of swallowing difficulties and impaired swallowing function on intimate behaviours. As this was a very new and potentially culturally sensitive topic to explore, having personal one-to-one interviews was deemed to be more likely to generate a comprehensive picture of symptom impact. Finally, given the nature of treatment-induced toxicities, which potentially affect speech, e.g., dry mouth and dysarthria, it was important to give each participant adequate response time for each question.

The participants were offered a choice of either a face-to-face or a telephone interview. Generally, there is a bias in favour of face-to-face interviews over telephone interviews in qualitative research (Novick, 2008). This preference is often justified for several reasons, including face-to-face interviews offering a chance to build rapport with the participants, a central feature of qualitative interviewing. Moreover, face-to-face interviews allow the interviewer to appreciate the contextual factors affecting the conversation, such as witnessing visual and non-verbal cues (Novick, 2008). These factors may contribute to the richness of the data and allow for a deeper understanding of the participants' responses (Novick, 2008). However, telephone interviews provide a sense of anonymity and therefore provide an opportunity to explore topics that are sensitive in nature, such as eating and drinking experiences during and post-HNC treatment. They are also cost effective, in addition to providing an opportunity to access hard-to-reach participants (Sturges and Hanrahan, 2004). The telephone option was given as a choice in order to allow the interviews to be conducted while I remained in the UK.

3.3.4 Topic guide development

All interviews were framed by a topic guide. The topic guide offered general guidance rather than a prescriptive schedule of questions. The guide covered themes and topics to facilitate focused discussions on particular issues, but it was also flexible enough to follow the responses of the participants in order to provide a deeper understanding of the varied aspects of their unmet needs. The topic guide was developed based on information in the literature (Boyes, Girgis and Lecathelinais, 2009; Brockbank et al., 2015; Ghazali et al., 2013) and in discussion with the supervisory team.

The topic guide comprised four sections (see Appendix C):

1- General: An introduction to the interview. This was an open introductory question to encourage the patients to talk about their cancer and treatment experience. It also asked about the nature and experience of their swallowing problems.
2- Services: Concerned the patients' experiences of services relating to their eating and drinking and the nature of their experiences.
3- Unmet needs: Discussed the needs of HNC patients with regard to swallowing difficulties and to what extent they had been met.

4- Conclusion: Offered patients the opportunity to add other issues relating to eating and drinking that were important to them, but were not covered in the guide.

3.3.5 Participants

Patients were selected for inclusion if they fulfilled the following criteria: diagnosed with oral cavity, pharyngeal or laryngeal cancers; adults ≥ 18; undergoing treatment or having completed their treatment; and fluent in either Arabic or English. Patients were excluded if they had significant cognitive or memory difficulties limiting their ability to engage in an interview. Those with non-curable disease (metastasised, or untreatable cancer) were excluded as they are a different population and interviewing them may pose specific challenges if certain issues emerge.

a. Sampling:

The recruitment strategy was to conduct a purposive and maximum variation sampling to cover a wide spectrum of HNC patients based on their treatment modality. This technique was chosen to capture all the needs as far as possible in this population, as different treatment approaches produce different functional outcomes (Chapter 1). The aim was also to recruit patients until data saturation was reached, i.e., 'information redundancy' (Francis et al., 2010; Saunders et al., 2018). Data saturation is achieved when there are no new information or data resulting from the interviews and when further coding is not possible (Fusch and Ness, 2015; Vasileiou et al., 2018).

b. Identification and recruitment of participants:

In health research, gatekeepers are usually healthcare professionals involved in the potential research participants' care, and they mediate between the researcher and the potential participant (Patterson, Mairs and Borschmann, 2011). It has been suggested that gatekeepers are important and can facilitate access to potential participants in addition to influencing how the research study is perceived (Høyland, Hollund and Olsen, 2015). As this was the first time such study takes place with HNC patients in Kuwait, and considering the intimate nature of the study, working with gatekeepers was crucial to ease access to patients and establish trust in the research.

Consecutive HNC patients at the Kuwait Cancer Control Centre (KCCC) out-patient clinic were identified based on their clinical characteristics. They were then approached by a

gatekeeper (head of radiation oncology department and/or his staff) who informed them about the study and asked if they were, in principle, potentially interested. I then met with the potential participants to formally ask them if they would be willing to participate in an interview about their swallowing problems.

Patients who expressed an interest in participating were then given a full explanation of the study details, and a patient information sheet (Appendix D). They were also given a chance to ask questions, and a cooling-off period during which they could think about their decision. After two working days, they were contacted again – with their approval – to establish their decision. Those agreeing to participate were asked about their preferred meeting option – face-to-face or over the phone, plus time and location. The participants opting for face-to-face interviews were given the option to select one of three locations: KCCC, the Physical Medicine and Rehabilitation Hospital or a private multi-disciplinary clinic, depending on their preference, and subject to room availability.

Patients who participated in the translating and adapting the MD Anderson Dysphagia Inventory study (MDADI, details in Chapter 4), and who were happy to be contacted for future studies were also approached and the same process was followed.

3.3.6 Interviews

Pilot interview:

Prior to conducting the interviews with the patients, I piloted the topic guide by conducting a face-to-face interview with a fellow speech and language therapy PhD student in order to practise my technique and skills. As a novice interviewer, this step was essential in order to identify the areas that required improvement and avoid negatively affecting the quality of the data (Patterson and Dawson, 2017). The pilot took 56 minutes, and the interviewee provided helpful comments about how to deal with certain issues.

Some of the suggestions made by the interviewee were to encourage a more natural conversation, avoid step-by-step questioning caused by exactly following the topic guide, and focus more on areas of interest. The interviewee also highlighted that the question regarding the effect of swallowing impairments on sexual intimacy might be an issue when interviewing the participants, especially male participants.

3.3.7 Data management

Patients' demographics and clinical characteristics were collected. Prior to beginning the interviews, the participants signed a consent form (Appendix D). To document online consent for patients opting for phone interviews, the participants were required to verbalise and confirm each of the consent points (Appendix E).

All of the interviews were audio-recorded using a digital recorder. As all the participants were Arabic speakers, the interviews were transcribed and translated into English verbatim by me in order to facilitate anonymised sharing with the research team. All of the participants were assigned a code against their names in a separate sheet, and this sheet was kept in a secure location separate from the transcriptions, audio-recordings and consent forms. In the transcripts, any details specific to the patients' demographics were removed, for example, country of origin, treating doctor, and names mentioned during the conversation. For the purpose of presenting the quotations here, the participants were given an alias instead of their real names.

3.3.8 Analysis

The analysis process followed the six-step process suggested by Braun and Clarke (2006). The summary of the guideline process is shown in Table 13 below.

Table 13 Summary of the analysis process suggested by Braun and Clarke (2006) on the process of thematic analysis

Step	Description
1- Becoming familiar with the data	- Transcribing the data, reading and re-reading - Writing down initial ideas
2- Initial coding	- Systematic coding and collecting data relevant to each code
3- Searching for themes	- Collect codes into potential themes - Gather information relevant to potential themes
4- Reviewing themes	- Check if the themes work in relation to the extracts, and the entire data set - Generate a thematic 'map' of analysis
5- Defining themes	- Refine the specificities of each theme and the overall story of the analysis - Generate clear definitions and names for each theme
6- Producing the report	- Final analysis - Selection of extract samples and writing a report.

The data analysis process was iterative throughout the study. After each interview, a preliminary analysis was conducted by going through the recording and reflecting on the responses of the interviewee and myself, in order to reconsider the direction of upcoming interviews and to make adjustments as required.

To ensure the reliability and validity of the results, I transcribed and coded all the interviews and shared them with a second researcher (JL), who also coded the transcripts. Common codes were collected under themes. Differences in the organisation of codes were discussed with JL and a consensus was reached. After assigning the codes to different themes, another discussion was conducted to make sure that all the results fitted the appropriate subthemes and categories. These were also discussed and approved by the supervisory team.

3.4 Findings

3.4.1 Recruitment

The recruitment plan was based on a purposive and maximum variation technique. This was challenging as the patient uptake was low. Initially, five potential participants were approached, and only two participated in the study. Because of this, eventually any patient who agreed to participate was recruited. Later, nine potential participants were approached, and only three participated in interviews, giving a total of five participants. The reasons for not participating were as follows: one patient was excluded for not meeting the inclusion criteria; other reasons were pain, fatigue, too busy or could not be reached by phone. One patient confused the word 'interview' with a broadcast TV interview. None of the approached participants welcomed telephone interviews as they felt that this would be too impersonal.

3.4.2 The interview

The interview process:

All interviews took place at the private clinic, as all participants thought it was a more relaxing environment than the hospital setting, and closer to where they lived. The interviews started with greetings and welcomes and a reminder of the interview purpose and the consent form. The participants were informed that they could stop at any time for breaks, or to terminate the interview. They were also invited to enjoy the refreshments available, and to ask if they needed anything else. Refreshment serving is common during

qualitative interviews, and it is a customary tradition in Kuwait to provide food and drinks to anyone who accepts your invitation (either social or work-related).

The interview started with a general question about their cancer and treatment journey, and then followed the interview guide, or picked up and followed the participants' responses. After asking the final question, which is 'Do you have anything else you would like to add', and participants were thanked and given a debriefing sheet.

Reflecting on the interviews:

In the first two interviews, I struggled with the first introductory question 'Can you tell me a bit about your experience with cancer and its treatment' as the participants tended to narrate their whole journey, which is quite understandable as it is a tough and long journey. However, this question was intended to be only an introductory question to facilitate the conversation and to establish a bond with the participant. I then consulted with my supervisors and informed them of my difficulties in steering the conversation away from the 'focus' question and to progress to the questions related to the interview aim. They gave me guidance on how to deal with such issues by taking control of the interview and gently moving away to the next question about swallowing.

Moreover, after conducting two interviews and reflecting upon the recordings and the participants' responses, it was decided in conjunction with the supervisory team to avoid questions about the effect of swallowing difficulty on sexual intimacy, as both initial participants were not comfortable with these questions.

My interviewing skills developed over time and I became more able to probe on specific areas of interest by open prompts like 'can you tell me why/more?', 'can you elaborate?', or 'would it be possible to go back to this X point you mentioned earlier?' In addition, as the conversations are about very personal and difficult period of the participants' life, it sometimes caused the participants to cry, sigh or pause. After this occurred in the first interview, I was better prepared to handle the situation and my response. I showed empathy and compassion, and gave the participants time to recollect themselves and continue the interview. I also informed them about the option of stopping the recording and the interview, however all were content to continue.

3.4.3 Demographics and clinical characteristics

Of the five interviewees, four had laryngeal cancer and one had cancer of the nasopharynx. All of the patients consumed food orally and none was tube dependent during their treatment. Two of the participants held a university degree, two completed high school, and one completed middle school*. All but one of the participants were smokers, two currently. The time post-treatment ranged from 0 to 21 months. Only one of the participants was undergoing treatment at the time of the interview, one patient was five months' post-treatment, two patients had completed one year post-treatment (13 months), and one had completed 21 months. The participants' details are in Table 14.

3.4.4 Themes

Using thematic analysis, three main themes were elicited from the data: 1) physical and functional changes and the emotional response towards these changes; 2) the experience of dysphagia management, specifically regarding information given and the actions taken by patients; 3) unmet needs: information needs, swallowing and other supportive care services. The first theme, 'physical and functional changes and the emotional response' focuses mainly on the changes patients faced with their swallowing abilities, and the emotional and social bearing of these changes. The second theme, 'experience of dysphagia management', includes two subthemes: patients' experiences of information they received regarding their swallowing difficulties, and actions taken to resolve and manage their difficulties. The final and the third theme involves the patients' needs, and specifically information needs, dysphagia services, and other supportive care services. Tables 15, 16 and 17 list the themes, subthemes and categories that emerged from this study.

* Middle school (ages 10/11 – 14/15), high school (ages 14/15 – 17/18).

Table 14 Demographics of the patients participating in the unmet needs interviews

Participant	Patient characteristics	Outcome
Zahra (57-year-old female)	Tumour site	Larynx
	Tumour Classification	T4N0M0
	Treatment type	Radiotherapy
	Smoking status	Ex-smoker
	Marital status	Married
	Education level	High school
	Time since treatment	13 months
Shayma' (44-year-old female)	Tumour site	Larynx
	Tumour Classification	T3N1M0
	Treatment type	CRT
	Smoking status	Never smoker
	Marital status	Married
	Education level	University
	Time since treatment	Five months
Saeed (52-year-old male)	Tumour site	Larynx
	Tumour Classification	T1N0M0
	Treatment type	Radiotherapy
	Smoking status	Persistent
	Marital status	Married/long distance
	Education level	Middle school
	Time since treatment	Current treatment
Rashed (50-year-old male)	Tumour site	Larynx
	Tumour Classification	T3N1M0
	Treatment type	CRT
	Smoking status	Stopped during treatment/ now persistent
	Marital status	Married
	Education level	High school
	Time since treatment	21 months
Zaid (27-year-old male)	Tumour site	Nasopharynx
	Tumour Classification	T3N1M0
	Treatment type	CRT
	Smoking status	Ex-smoker
	Marital status	Single
	Education level	University
	Time since treatment	13 months

Theme one: Physical and functional changes and the emotional response to these changes

Patients in this study have experienced a range of problems related to their swallowing abilities. The changes reported by the patients are commonly reported in HNC literature. The patients reported that these changes limit their ability to eat, drink and enjoy food.

When asked 'what do swallowing problems mean to you?', one participant, summarised it in two words:

> *'Choking and pain.' (Shayma')*

Some of the other problems described related to swallowing were: mouth dryness, changes in taste and smell, painful swallowing and dietary limitations. Mouth dryness was a difficult and persistent issue with the participants, especially at the beginning of the day, even at almost two years' post-treatment. In fact, all of the participants had bottles of water with them during the interview and some requested more water when their bottles were emptied. All of the participants stated that they always carried water with them in order to manage mouth dryness, and they had to drink large quantities throughout the day. For example:

> *'I'd drink 3–4 litres of water per day. Maybe more. I carry water with me for 24 hours.' (Rashed)*

Additionally, eating, while experiencing changes in taste and smell due to treatment, was described as:

> *'It felt like I was eating water, there was no taste, or smell.' (Zahra)*

Painful swallowing was frequently reported by the participants in this study. The pain was associated with dry swallows and with food/liquids:

> *'Also, when I swallow my saliva it is painful. I feel like there is fire (pointing at his throat).' (Saeed)*

> *'I couldn't even swallow my saliva, I couldn't swallow water. The pain, the pain was persistent for a very long time. (Shayma')*

Painful swallowing was described figuratively using expressions like: 'burning', 'fire', 'knives' and 'needles'. Zaid described it mechanically as:

> *'I felt like my throat stopped working.'*

Patients also reported changes in their diet and eating habits in comparison with before treatment. Zahra had to eat food that she did not like as she did not have many options. She said:

> *'I hate pasta, but I couldn't eat anything else.' (Zahra)*

Three of the participants reported that during and after treatment it took them longer to finish meals. For Zahra, this stopped her from eating in front of others. She explained:

> *'It would take me two to three hours to finish a meal, how am I supposed to do that in public?' (Zahra)*

Four participants reported that they felt embarrassed about the physical changes and/or new eating habits, preventing them from being with others. However, this was not the case with their immediate family, only with their extended family members and friends. For example,

> *'The pain was difficult … (sigh) When I got invited to places it was very, very difficult. Swallowing was difficult. I had to drink water, and sometimes the water would come out of my nose.' (Rashed)*

As a result of these changes, participants described feelings of loss, frustration, irritation, anger, worry and embarrassment. The participants were also keen to know what to expect from their recovery and looked for signs of improvement.

Saeed, the participant undergoing treatment, said:

> *'Maybe when I go to the pain clinic [referring to the pain management clinic he was referred to] I would have pain, but it won't be for 24 hours. Because some pain is ok! I am getting cancer treatment so that is expected. I know that the painful swallow would get better after treatment. This is what they [his doctors] told me. They said two weeks after radiation everything will be better.'*

Similarly, Zahra said that she was expecting her issues to be resolved after completing her treatment, but she was disappointed. She said:

> *'When I went to [back visiting her home country], I went to the shop and got the fruits and veggies that I liked. I cried! I cried like someone died. I looked at them, tasted them, but there was no taste! Nothing! You know they told us that this will happen. But I thought it's only during treatment, not after treatment. So I was excited to complete the treatment and try these and feel the taste of heaven, but I couldn't taste anything!' (Zahra)*

Shayma' reported that during treatment and shortly after, she was afraid of choking while eating or drinking. She said:

> *'Sometimes when I ate, even with water, it was difficult to swallow and would take time. It used to go down slowly. I'd get scared. [scared of choking].'*

Other quotes can be found under their related subtheme/category in Table 15.

Table 15 Theme one: Physical and functional changes and emotions towards these changes

Subtheme	Category	Quotes
Swallowing, eating and drinking changes	Mouth dryness	-ZAHRA: You know what was difficult as well? Waking up and having my mouth all stuck together. I had to separate things with my hand. -SHAYMA': I couldn't swallow my saliva, not just food, even my saliva I couldn't swallow. -SAEED: While sleeping … I feel like I'm choking.. I don't know if swallowing muscles close while sleeping. -ZAID: Especially at the beginning of the day [Replying to a question about dry mouth].
	Sensory changes	-ZAHRA: 'Also, the food had no taste, why would I go eat outside?' -ZAHRA: It felt like nothing in the world matters against feeling the taste of food in your mouth. -ZAHRA: When you eat you smell, I used to look at the food, and the smoke coming out of it, but I just couldn't smell it. It felt like you're looking at something closed. -ZAID: The taste, I couldn't feel it.
	Painful swallowing	-ZAHRA: Your eyes would pop, you know, you can't it's like you're choking, especially with the first few bites. -SHAYMA': I need to make an effort to swallow. -SHAYMA': My throat would hurt from the inside, and my neck would hurt from the outside. -SAEED: I suffer while eating. -SAEED: I feel like there is a needle in my throat. -SAEED: So now I am not concerned about my swallowing as much as I am concerned about the pain when I am swallowing. -RASHED: Regarding my swallowing, now it's fine there is nothing wrong, but sometimes, sometimes not always, when I swallow for the first time I feel some

		pain, but then the second swallow is easier, and like there is nothing wrong. -RASHED: … and this is what's causing swallowing pain. When compared to the previous pain, it's like nothing. When I think about it, it's nothing. [referring to pain after treatment in comparison to before treatment]. -RASHED: I swear I felt like knives in my throat. -ZAID: I felt like my throat wasn't working. -ZAID: One bite was a disaster.
	Changes of eating habits and dietary restrictions	-ZAHRA: I used to look at water wanting to drink it, but I just couldn't. -ZAHRA: I would have small bites, I'd cut the pasta onto tiny pieces. You know what's my favourite? Sour juices; orange juice, and lemonade. This was all forbidden. It was sad. I would drink banana with milk. If you ask me what do you hate the most? I'd say milk. But I had to do it. Aah it was so difficult. So my eating, it was difficult. -SHAYMA': I carried water with me everywhere, with every bite, I'd drink water. -ZAID: I had to eat soft food [After treatment]. -ZAID: I still have swallowing problems. I must drink water, if I want to eat I have to drink water. Before [cancer] I never drank water while eating. -ZAID: Sometimes it's difficult [Replying to a question about food preparations with family].
	Eating time	-ZAHRA: A bowl of soup would take two hours to finish. -SHAYMA': Sometimes when I eat, even with water, it was difficult to swallow, and it would take time. -ZAID: Previously, I used to take a long time to eat, I still do, but now I do go out and eat.
	Restrictions of social life	-ZAHRA: It was embarrassing, not with my family, but when eating outside [Referring to eating outside]. -SHAYMA': At the beginning, I used to avoid going to the Zwara [family gatherings]. -RASHED: I stopped going. [Referring to Diwaniya].

		ZAID: I did previously [stopped going to public places]. Previously, I used to take a long time to eat, I still do, but now I do go out and eat. [Referring to eating in public].
Emotional response to changes in swallowing	**Adverse feelings**	-ZAHRA: If you ask me what's the hardest thing about having cancer, I'd say this stage … [Referring to not being able to enjoy food]. -ZAHRA: I would be upset and tell them: please no one asks! I want to forget [when people ask her about swallowing difficulties]. -ZAHRA: I remember looking at the sky and talking to Allah [god]: 'please, just one bite! I just want to feel the taste of one bite!'. -ZAHRA: It felt like nothing in the world matters against feeling the taste of food in your mouth. -ZAHRA: …You know what's my favourite? Sour juices; orange juice, and lemonade. This was all forbidden. It was sad …. -ZAHRA: I remember telling the doctor why didn't you tell me that it was going to be this horrible? I would've eaten a lot before treatment! He laughed, but I meant it! no taste, no feeling, no smell, swallowing was painful! -ZAHRA: During mealtimes, they would look at me and ask: are you ok? I would be upset …. -SHAYMA': Actually, just remembering these days I shiver because of all the suffering. It was scary. -ZAID: I was worried. I wasn't scared, but I was worried. -RASHED: I'd drink water, I'd wait for a while, I became really upset with myself. I'd pray to Allah [god]. There is nothing I can do, there is no solution. -RASHED: I became irritated, upset!

Theme two: Experience of dysphagia management

In this theme, the participants talked about their experience with dysphagia management, the information they received regarding swallowing changes and abilities without asking, and the actions they took in relation to managing their difficulties. Some participants thought that the information they received regarding the changes that would occur was useful, while others thought that the information was insufficient, or not useful. Rashed thought that some of the recommendations were helpful. This was illustrated by him saying:

> *'The doctor used to tell me to stay away from bread, because it's dry. So he'd say eat rice … potatoes, because they're soft.'*

But he also felt that the information was not sufficient:

> *'I didn't feel like there was enough information.'*

Moreover, in relation to the supplements he was given:

> *'… […] gave me milk for nutrition. It wasn't something scientific. This is for radiation, this is for chemo, this is for swallowing. There should be someone dedicated to do this.'* (Rashed)

Zaid also felt that the information was lacking, he said:

> *'Like, they used to tell me to eat soft food. But there wasn't something specific.'*

The way the participants chose to deal with the difficulties they faced was different for each participant. Some went back to their doctors to ask for help, and others decided to self-help by going online to seek information. One of the participants used natural remedies to ease her pain.

Zahra reported that when she had swallowing difficulties, she informed the doctor and asked about the problem. But she also depended on the internet to find information. She says:

> *'I also saw the doctor and asked about my swallowing difficulty. He said that it's okay, it will become better eventually. So I went to the internet, and read that it will take some time. It was different than what the doctors have told me'.*

Zaid went on a learning journey about what he could do to improve his swallowing difficulties. He depended largely on the internet for information. He said:

> *'On YouTube there was something called 'swallowing ... swallowing therapy' or 'swallowing doctor' like exercises and stuff, and then I realised that the throat is like muscles, and I read, I learned that … that it is a mechanical process or something like that. So I tried to do the exercises, maybe they helped I don't know. I think like I think they did. Like how to swallow and stuff. There is like a specific way. This also helped.'*

The participants also explored different strategies to deal with their problems. For example, Zaid had a trial-and-error period, where he tried different foods to explore what he could manage.

> *'I remember buying everything [different food items] just to try them. Later on, I had a collection, I knew what I can and can't eat.'* (Zaid).

Zahra also found a way of dealing with her xerostomia. She said:

> *'Do you know what I liked? Cucumbers! So I'd peel it and suck it, because it helped with my dry mouth. Also, it tasted nice. I wasn't able to chew on it, you know how old people or babies would suck on things? I was doing the same.'*

In Table 16, other quotes are presented regarding the patients' experiences of managing dysphagia.

Figure 8 Examples of the methods patients relied on to reduce oral symptoms

'Do you know what I liked? Cucumbers! So I'd peel it and suck it, because it helped with my dry mouth. Also, it tasted nice. I wasn't able to chew on it, you know how old people or babies would suck on things? I was doing the same.' (Zahra)

'I used pomegranate skin, with myrrh [natural herb] … honey and olive oil … this reduced my pain by 50%. [Referring to oral pain].' (Shayma')

Table 16 Theme two: Experience of dysphagia management

Subtheme	Category	Quotes
Information given without asking	**Useful**	-SHAYMA': They were helpful for sure. [Information given by the doctors and radiologists]. -SAEED: They told me that swallowing will become more difficult.
	Not useful	-ZAHRA: They told us to eat 5-6 times per day, but we don't know what to eat? -SHAYMA': To tell me exactly and in full details about what would the radiation do to me … I did not expect my throat would close, like nothing would pass.
Action taken	**Self-help**	-ZAHRA: So then I started reading, and I read that this is common. [Swallowing problems after treatment]. -SHAYMA': I used pomegranate skin, with *morra* [natural herb] … honey and olive oil … this reduced my pain by 50%. [Referring to oral pain]. -RASHED: I would use Google, YouTube, whatever, and my friends would send me some information too. -ZAID: I used to try a lot with food, to explore what I can and can't eat.
	Asked for help	-ZAHRA: I also saw the doctor and asked about my swallowing difficulty. He said that it's okay, it will become better eventually. SHAYMA': In my follow-ups I would ask the doctors [about her swallowing difficulty], but honestly, I would go online and look things up as well … It was so detailed'
	Did not ask for help	-RASHED: nothing. [replying to a question about choking while eating]. I'd drink water, I'd wait for a while, I became really upset with myself, I'd pray to Allah [god]. There is nothing I could do, there is no solution. -RASHED: I am not very well-educated. And add to that the shock … They should tell me everything. I did not feel like there was enough information. ZAID: But like the side-effect, like they're known. I don't have to ask the doctors, they should ask or tell me about what's available.

Theme 3: Unmet needs

The final theme relates to two main sub-themes: 1) informational needs, and 2) supportive care services needs.

Informational needs

Patients stated that having written information, in addition to verbal information, could be helpful as then they could go back and re-visit the information as much as they needed.

> *'You tell the patient verbally, and then the patient would go home and read again [brochures]. They will register the information.'* (Shayma').

Zaid suggested that a website or an online resource could be helpful to the patients:

> *'They could tell us to go online. To read, or to give me like you have this type of cancer, you'll have these problems.'*

Zahra also mentioned that having posters on the walls in the waiting rooms would be useful. Regarding the time of information delivery, having the information from the very beginning was preferable.

> *'They should've given us all the information from the beginning.'* (Zahra)

Supportive care services needs

When asked about dysphagia services, four patients agreed on the importance of being seen by someone with specialised knowledge of swallowing, and having follow-up throughout their treatment, or until they started to feel better. They thought it would be valuable to see someone from the beginning, before starting treatment, to get information about the possible side-effects, and to obtain food recommendations to help them deal with their altered diet.

> *'There should be someone specific for swallowing … this was not available, and it is unprofessional.'* (Rashed)

Zahra also agreed by saying:

> *'They should be close and available to give us at least some information and advices regarding the difficulties we're going to face' [referring to swallowing services].*

Zahra also said:

> *'Food plans would've been helpful. Because we can't eat. And we're tired. So they can give us like recommendations and meal plans to make our life easier.'*

Shayma' suggested a preparatory session for the patients:

> *'… The supplements, the type of food … before treatment, there should be like a preparatory session.'*

Shayma' also stated that she preferred having someone who was specialised in swallowing to talk to her about her difficulties. She said:

> *'There is a saying [a proverb]: 'give your dough to the baker'. I prefer someone who is specialised to come and talk to me … because they will provide me with detailed and very specific information' [referring to dysphagia services and counselling].*

Other supportive services

The patients also mentioned the importance of other ways of getting support such as talking to other patients. For example, Zahra believes that support is vital in cancer care. She expressed her thoughts by saying:

> *'It's not about help, it's about support, the most important thing in cancer treatment...'*[†]

Zahra also explained:

> *'… I found it useful, and they also found it useful. Because we [patients in the waiting room] used to exchange experiences, one person would say that I drink this, the other would say I do that. Also some natural things that we can do' [natural remedies].*

Shayma' was of a similar mind, as she said:

> *'Emotional support. This is what every patient needs.'*

[†]The participant here differentiated between 'help' (musa'ada in Arabic) and 'support' (sanad in Arabic). The literal translation of the word *'support'* or *'sanad'* in Arabic, is 'to lean on', whereas *'help'* or *'musa'ada'* means 'assist'. While the two terms can be synonyms or share similar meanings in English, the term 'support' may indicate an incorporeal and sustainable assistance that could be unmeasurable, rather than something measurable such as in 'help'.

Shayma' described her experience of how she felt about a lady (a fellow patient) who approached her:

> *'A lady … told me she wanted to talk to me … Allah [god] sent her in my way. It was so empowering and inspirational. I felt really stronger afterwards.'*

Psychological support from professionals was also mentioned, and the potential for a dedicated clinic

> *'You'd wish for a psychologist, or a room, a clinic, that assesses your case. What are your needs? How are you affected? What do you want?' (Rashed)*

Table 17 offers more quotes from the patients.

Table 17 Theme three: Unmet supportive care services needs

Subtheme	Category	Quotes
Information	Level of detail	-ZAHRA: They told us to eat 5-6 times per day, but we don't know what to eat? -SHAYMA': To tell me exactly and in full details about what would the radiation do to me … I did not expect my throat would close, like nothing would pass.
	Preferred method of delivery	-ZAHRA: I feel like having things on the wall saying about swallowing problems would be helpful. -RASHED: 'I didn't get any brochure. They should have … for the patients. Information and guidance about what to eat and what not to eat.' -SAEED: Verbally, of course. [Referring to method of information delivery].
	Timing	-ZAHRA: They should've given us all the information from the beginning. -SHAYMA': 'A lot of the information should be given before treatment.' -SHAYMA': … I would be more prepared. So I won't get surprised or shocked [Referring to information given before treatment].
Services	Available dysphagia services and information	-ZAHRA: Yes, from the beginning. The doctors should've told us even before referring us to treatment. SHAYMA': If there is a specific way of eating, types of food, exercises [advice and information regarding swallowing]. -RASHED: They should have. For the patients. Information and guidance about what to eat and what not to eat. -ZAID: I feel like there should be someone to follow-up with the patient until he's settled 100%. I feel like this is good.
	Psychological and peer support	-ZAHRA: It would be helpful. (To get info from someone who've been through the same experience). -SHAYMA': Yes a lot, because they are patients like us, and Allah [god] treated them. So when you see them with your own eyes you'd believe, it's different from just hearing about them.

-RASHED: 'You need to support patients emotionally before even starting treatment. So they can tolerate treatment.'

-ZAID: And there was.. later I found a support group online, on Facebook for head and neck … This was really nice. We don't have this here, in Kuwait.

Additional concerns

Although the interviews focused on swallowing, other concerns and topics emerged during the discussions that participants thought needed addressing. These were not reported under a theme as they are not within the scope of this PhD. However, they are important enough to require attention, and they should be considered when lobbying for supportive care services.

For four participants, voice problems were a source of concern. Voice problems were a cause of miscommunication and embarrassment, and they triggered other negative feelings. These issues were either before treatment and/or afterwards.

> *'My main concern was that I may lose my voice! Because I love talking. I'd go crazy without my voice' [pre-treatment]….. I was upset whenever I was speaking or eating.'* (Zahra)

Shayma' was annoyed by people asking about her voice, losing her voice was a cause of miscommunication:

> *'It wasn't eating or drinking that caused me problems in public, it was my voice! Because I didn't have my voice, and people were nosey….. I told her [the doctor] you didn't understand me, and I wasn't able to basically talk. I want to say something, but I couldn't, and they don't get you.'*

Similarly, Saeed reported that during pre-treatment he had voice problems:

> *'It was only my voice, I couldn't talk. It was very difficult … (sigh)' [pre-treatment].*

Voice issues also triggered feelings of frustration in Rashed, who stated:

> *'I started to become very angry. Because I'd talk with you and you couldn't hear my voice! So I started to become very frustrated!'*

One participant reported hearing problems (a common side-effect of NPC treatment). He said:

> *'My hearing is still affected. I cannot hear loud sounds. If someone is standing next to me and speaking loudly I'd hear a noise in my ear.'* (Zaid)

This stopped him from going into noisy environments such as the movies, or crowded places.

A positive relationship with healthcare professionals was influential, helping patients tolerate the journey:

> *Zahra: 'The doctors there were amazing, everyone was. They treated us like family. It wasn't only me, I used to see how they treated other patients. We were like family members to them. They never got tired! They were genuinely nice and good people.'*

The impact on mood was substantial, particularly during gruelling treatment, with one patient saying they had contemplated ending their life:

> *'….The second chemo was very difficult, but the third one… the third one I thought about suiciding. I didn't want to live. I swear I thought about suiciding. It was horribly painful, I was vomiting the whole time, I wasn't able to eat. I couldn't eat.'*

3.5 Discussion

Dysphagia remains a prevailing effect of HNC and its treatment, and patients are often required to adjust to a 'new normal' in terms of eating and drinking during and after treatment. In order to adjust and cope with dysphagia, patients often require supportive care services to help reduce the emotional and physical burdens of this symptom. The findings of this study describe the dysphagia experience and unmet needs of HNC patients living in Kuwait. All of the participants in this study stated that they had experienced some degree of difficulties with swallowing at some point throughout their cancer pathway. The findings can be summarised under three interrelated themes: 1) physical and functional changes and the emotional response to these changes; 2) experience of dysphagia management; and 3) unmet needs. This is the first study to report on the dysphagia experience and the unmet needs of HNC patients in Kuwait, the findings however are similar to that reported in other studies (Crowder et al., 2021; Einarsson et al., 2018; Dornan et al., 2021; Kristensen et al., 2019; McQuestion, Fitch and Howell, 2011; Nund et al., 2013; Ottosson et al., 2013; Patterson et al., 2015). Understanding patients' experiences and needs is beneficial in planning health interventions, and for providing patient-centred care.

3.5.1 Physical and functional changes and the emotional response to these changes

Difficulties in swallowing were associated with a sense of loss. The losses experienced by the participants were physical, functional, emotional and social and they resulted in adverse feelings. Physical and functional losses were related to treatment-related toxicities and having to accept the fact that mealtimes and food meanings had changed. These physical and functional losses led to an emotional loss of the enjoyment of eating and drinking. The patients also had to accept new mealtime habits, food textures and foods they previously disliked in order to maintain their weight and survive. Some participants lost their social life due to reduced self-confidence, feelings of frustration and embarrassment. These losses are commonly reported in studies exploring eating and drinking in HNC (Crowder et al., 2021; Dornan et al., 2021; Kristensen et al., 2019; McQuestion et al., 2011; Nund et al., 2013; Ottosson et al., 2013).

In Kuwait, social life does not only revolve around immediate family and close friends. Almost every aspect of living is considered to be a social activity. Food and drinks are

available everywhere, i.e., shared meals at the workplace (during breakfast, snack or lunch time), weekly large family gatherings, including immediate and extended family members (*Zwara*), and weekly (on certain instances daily) gatherings of male friends and acquaintances (*Diwaniya*). In general, one can avoid or limit the social activities surrounding food at the workplace, but 'Zwara' and 'Diwaniya' are two fundamental and cultural concepts in Kuwait, and people are often expected to eat and drink the available food. Individuals can bring their own meals, but this may be associated with a sense of embarrassment, especially if it is not 'normal' food. In the current study, the participants reported avoiding these social events due to their emotional and physical losses. This avoidance may create a sense of isolation and a reduced feeling of belonging. Social isolation as a consequence of dysphagia have been reported previously (Crowder et al., 2021; Hiatt et al., 2020; Patterson et al., 2015).

3.5.2 Experience of dysphagia management

The participants described different experiences of how their swallowing problems were managed. They also described different strategies to self-manage their symptoms, and this journey of discovery required time to identify and adjust to. One of these techniques was increasing water intake, with the need to constantly carry a bottle of water to increase lubrication, facilitating speech production and ease eating. Similar methods have been reported in the literature (Jiang et al., 2017; Ottosson et al., 2013). In this sample, the participants also reported self-managing the symptoms by using natural products such as peeled cucumbers to stimulate salivation and promote hydration, and other products, e.g., olive oil and honey. There is some evidence to suggest that products enriched with olive oil (Navarro Morante et al., 2017) and honey (Ackerman et al., 2018; Jiang et al., 2017) can offer a therapeutic effect for patients with xerostomia and a brief pain relief from mucositis, respectively.

Trusting 'complementary and alternative medicine' to manage symptoms was also reported. The use of such medicine is relatively common in some regions, including Kuwait. This practice is often based on anecdotal evidence passed from older generations, personal research, and/or asking a specialist in this practice. One of the participant stated that she used the natural herb 'Myrrh' to ease her oral pain. This natural herb is used in alternative medicine as an anti-spasmatic agent (https://www.healthline.com/nutrition/myrrh-oil). In fact, two other participants reported an interest in complementary and alternative

medicines but in their case, it was to manage or cure cancer not dysphagia. One asked his doctor and was advised against it, and the other decided not to use it because she was not sure of its benefits or harm. It is important for doctors and other healthcare professionals to be aware of this interest, so that they can thoroughly describe and discuss the harms and value of using such alternatives in a non-judgmental and constructive way. During a delicate time, such as cancer treatment, it is important to understand how to properly incorporate or dismiss the use of such alternatives. An example of this is the use of raw camel milk, which is relatively common in some societies, including Kuwait's.

Other strategies to self-help and cope encompassed reducing meal and bite sizes, changing eating habits, e.g., by giving up some foods and beverages and adjusting to consuming new or previously disliked items and textures. The participants also had to go through a trial-and-error phase with food purchases to learn what they could or could not manage. Similar strategies have been reported elsewhere (Einarsson et al., 2018; Ottosson et al., 2013; Patterson et al., 2015). Gathering such experiences from individuals and informing other patients can save time spent on discovery, reduce stress, and save money. It is important to consider the financial aspect associated with the journey of 'trial and error', as individuals with financial difficulties may not have the privilege of purchasing different types of food (Crowder et al., 2021).

Additionally, some participants stated that they did not ask for help from their healthcare professionals and were disappointed, expecting their treating doctors to inform them of the difficulties that they might face. For example, one of the patients linked the fact that he did not seek for help to his level of education. Possibly implying that he did not know how to ask questions, or was unaware of who to approach. Previous studies on different cancer patients had contradictory results on the correlation between level of education and unmet needs. While some studies found that higher education was associated with more unmet needs (Willems et al., 2015) other studies found the opposite, that lower education was associated with higher unmet needs (Matsuyama et al., 2011). This was difficult to explore in the current study due to the small sample size. Healthcare professionals should be aware of this, and constantly support their patients and empower them to take control of their health.

It was not unexpected that the participants in this sample referred to god ('Allah' in the Muslim religion) throughout their discourse. It has been previously reported that patients

resort to their religious beliefs in order to cope with their diagnosis and deal with their symptoms. The role of religion in coping with cancer diagnosis has been explored in previous studies, and it is suggested that religious beliefs play a role in coping and maintaining hope (Chen et al., 2012; Kwok and Bhuvanakrishna, 2014). Furthermore, culture and religion can shape the meanings and perception of pain. For example, pain can be viewed as a test of faith or as a punishment for wrongdoings, and the person experiencing the pain should confirm their loyalty to god by being tolerant and becoming closer to god (Koffman et al., 2008). This may hinder the person from seeking help, or expressing the full extent of their pain, which may result in more unnecessary suffering. Healthcare professionals should spend time to understand their patients narrative and consider a positive dialogue to help the patients.

3.5.3 Unmet needs

The feeling of loss may be heightened and adapting to a 'new normal' may be more stressful if patients have unmet supportive care needs. In this study, there were two types of main unmet needs and these will be discussed in the following sections.

Informational needs

A critical informational component is related to the changes in swallowing that may occur as a result of treatment toxicity. The patients in this study were generally not satisfied with the information offered to them, and they felt that the depth and number of details that they were given were insufficient. This resulted in them taking action by either asking their treating doctors or looking for answers themselves. The evidence in the literature is conflicting regarding patients' satisfaction with information provided, as some report the need for more counselling and pre-treatment information (Chen et al., 2012) and others report that patients are generally satisfied with the information they receive regarding dysphagia (Brockbank et al., 2015; Jabbour, et al., 2017). However, this is expected due to difference in practices in different treatment centres and countries. In Kuwait (during the data collection period), the role of providing information is typically assigned to the treating oncologist and/or the radiation specialist, who often describe all possible treatment-related toxicities, including dysphagia. However, they may not provide an elaborative and detailed description of this symptom, its side-effects or its impact on physical, functional,

emotional and psychosocial levels, its expected trajectory or how to manage it. This is not surprising as this role is mainly fulfilled by the SLT, who should be an expert on this matter.

Furthermore, the duration / persistence of swallowing difficulties was not made clear to the patients, as some understood that the issues would only be present during treatment and would resolve shortly after treatment termination. This is in accordance with previous literature (Brockbank et al., 2015; McQuestion et al., 2011). It is difficult to estimate how long the problems will persist or what side-effects to expect on an individual level. However, it is important to be transparent with patients and to inform them about what is known and what is not, in order to avoid confusion, especially as persistent symptoms are open to misinterpretation as a sign of treatment failure (Patterson et al., 2015). There is some evidence suggesting that factors such as pre-treatment dysphagia, radical treatments, and tumour location can predict swallowing outcomes in the short and long term (Chapter 1). Such information can provide a base for information delivery.

There is some evidence suggesting a preference for verbal information (Brockbank et al., 2015; Pollock et al., 2011). Verbal delivery of information provides an opportunity to deliver tailored information and to allow for an open discussion, rather than the general information usually provided in written form (booklets or brochures) (Jabbour et al., 2017; Pollock et al., 2011). In the current study, all but one participant reported that they would prefer to have both verbal and written information. A reason for this preference is that written information can serve as a later reference for patients, especially as they may not register all the information at the time of receiving shocking news such as cancer diagnosis. Also, it can be referred back to (Brockbank et al., 2015; Jabbour et al., 2017; Pollock et al., 2011).

The patients in this study did not receive any written educational materials regarding their swallowing difficulties. In fact, no such booklets or information sheets were available at the KCCC during the data collection period. As a result, all the patients accessed online resources to understand and get information about their swallowing difficulties. Online resources are useful, accessible and convenient (Jabbour et al., 2017); however, not all patients have internet access, and many may require guidance on where and how to access this information. Therefore, both guiding patients and providing access where needed to such materials is important in order to meet their needs and to ensure that they have appropriate and evidence-based information.

Importantly, the patients in this study reported a lack of practical suggestions for how to apply the information they received in daily life. This should therefore be considered when providing written information, as this should include practical suggestions such as easy-to-eat consistencies.

Regarding the time of delivery of information, the participants in this study reported a preference for pre-treatment information, as this would allow them to be better prepared to face the side-effects. However, this requires thoughtful planning as there are individual preferences regarding the preferred time of delivery of such information (Brockbank et al., 2015; Ottosson et al., 2013). The notion of individual preference is still under-researched and requires further exploration to provide the optimal patient centred care, supported by shared decision making.

Supportive care services

The participants also reported the need for several supportive care services, including impairment-related services (dysphagia and oral symptoms) and psychosocial services (peer and emotional/psychological support). In this sample, the patients wanted access to healthcare professionals who were skilled and knowledgeable about the ramifications of HNC treatments with reference to swallowing. This was in line with evidence from the literature (Crowder et al., 2021; Pateman, Ford, Batstone and Farah, 2015). The majority of patients in this sample reported a lack of nutritional support and counselling about the treatment side-effects on swallowing, and a lack of practical suggestions for dealing with these side-effects. This also intersects with the information needs discussed above. Qualitative studies focusing on the eating and drinking experiences of HNC patients stress on the importance of ongoing professional support throughout the continuum of care (Crowder et al., 2021; Moore, Ford and Farah, 2014; Nund et al., 2014), with the suggestion that there should be an extended period of follow-up for patients receiving (C)RT (Chen et al., 2012). Healthcare professionals provide valuable support and guidance for patients during a vulnerable period of their lives, and this can reduce the feelings of loneliness and distress (Lang et al., 2013).

Patients also highlighted the importance of peer, emotional and psychological support, emphasizing the value of sharing and exchanging experiences with peers in the waiting room. It was felt that exchanging information was a source of comfort and empowerment and of value for the patients. Peer support can provide a positive experience during

treatment, and it can also be a source of emotional, practical and informational support, in addition to helping fellow patients tolerate treatment side-effects (Egestad, 2013; Lang et al., 2013; Pateman et al., 2015).

There are no such organised cancer support groups at the KCCC, except for one group, and not many patients are aware of it. There have been individual efforts from cancer patients to provide peer support, but this is mostly unorganised and therefore not every patient knows about the group's existence or feels comfortable enough to participate in these groups.

After identifying the multifaceted impact of dysphagia on individuals with HNC, and their perceived needs, it is important to consider how these needs can be met, and how to advocate for our patients to provide patient-centred care, and improve outcomes (Dawson et al., 2020).

Other concerns

The participants highlighted other concerns and topics including voice and hearing problems, relationship with healthcare professionals and one patient reported having suicidal thoughts. These topics are commonly reported in the literature. Building and maintaining a positive relationship with their healthcare professionals was reported elsewhere as being important to patients (Bressan et al., 2017). It is also reported that patients with HNC have substantial voice problems (Zebralla et al., 2021), hearing problems are also common (Chaibakhsh et al., 2018) due to treatment. Sadly, many patients with cancer have suicidal thoughts (Vehling et al., 2021). These topics and concerns require special attention and consideration.

3.6 Limitations

Although this study helped to shed the light on patients' experiences and needs, it has some limitations that need to be addressed. Qualitative interviews generally aim to uncover and understand specific experiences, and although this study initially aimed to recruit HNC patients using purposive sampling in order to understand their different experiences, it was not possible. The sample size of this study is small, and therefore data saturation was not reached. The limited sample comprised mostly of laryngeal cancer patients. As the results of my first study suggest (Chapter 2), laryngeal cancer is the second

most common HNC site, to oral cancer. This study unfortunately had no oral cancer patients, and therefore the experiences and needs of this group in Kuwait remain unexplored. It is important to consider how to best engage and attract patients in Kuwait to participate in research.

3.7 Clinical implications

Patients require support, and an interdisciplinary team management of their eating and drinking difficulties. Moreover, it is important to consider the importance of psychological and peer support, as evident from the results many patients would have benefited from these supportive services. It is important to probe the patients and ask directly about their swallowing problems, and perhaps use a Patient-Reported Outcome measure to facilitate discussions, and promptly tackle the difficulties the patients are facing.

In the next chapter, I will introduce a dysphagia-specific quality of life measure that can be used in clinical practice to facilitate discussions and to understand the psychosocial impact of eating and drinking on the patients. There also needs to be a way to meet the patients' needs in form of accessing information, and supportive services.

The findings highlighted that patients need information access, and therefore, it is important to develop and collate information for the patients, in order to be distributed for all HNC patients. Such materials can be developed by SLTs and other healthcare professionals in addition to patients working together. These can be used in conjunction with verbal information for the aim of providing a tailored and a personalised information for each patient.

3.8 Implications for future research

Due to the cross-sectional design of this study, and as the majority of patients described their experiences in retrospect I was not able to capture a longitudinal trajectory of needs throughout the treatment journey and during survivorship. Future research should consider a prospective research design, in order to capture the specific experiences and needs for each period. Future studies should also focus on survivorship needs, and provide emotional, function, physical and psychological support for patients with HNC.

Moreover, future research should include a purposive sample of the diverse HNC population in terms of social backgrounds and ethnicities, in order to be more inclusive and representative of all HNC patients in Kuwait. For example, I did not interview anyone from an Asian background. As a result, further research is indicated as this group comprise 36% of the population (Chapter 2, section 2.4.2, Table 4). Social eating experiences should be studied more in depth, as the social life in Kuwait is varied and includes weekly family and friends gatherings.

As none of my participants required tube feeding during or after their treatment, the experiences and unmet needs of people who are tube dependent are unknown.

Although this study was mainly focused on dysphagia, other issues, important to patients arose such as communication and voice problems. Future research should also consider performing an in-depth analysis of these experiences, in order to fully understand the patients experiences and to improve supportive care services. And finally, future research should take into consideration the caregivers, and their needs as living and dealing with patients with dysphagia requires adapting to new life style, and affect social events and shared meal experiences (Nund et al., 2014; Patterson et al., 2012).

Chapter 4: Swallowing Outcome Package: Patient-Reported Outcome Measure

The results of Chapters 2 and 3 suggest that swallowing may not be appropriately assessed, and hence underreported and underestimated in patients with head and neck cancer (HNC), and that patient needs often remain unfulfilled. It is important to properly assess dysphagia using simple and consistent measures in order to provide the appropriate management. As a main output for this thesis, I intent to develop a multi-dimensional Swallowing Outcomes Package for use in Kuwait's clinical practice. This package will include three swallowing outcome measures, each will be described in a separate chapter.

A key assessment method is a specific patient-reported outcome (PRO) on dysphagia. As none are currently in use in Kuwait, I investigated common swallowing PROs to select one as part of my planned package. This chapter describes the selection and adaptation of a dysphagia-specific PRO for use in Kuwait.

4.1 Literature review

Swallowing is a multifactorial function and thus requires multidimensional assessment to obtain a holistic assessment of the type and severity of dysphagia. Clinical swallowing evaluation and instrumental assessments are key to determining the presence and nature of a swallowing impairment. However, these methods do not capture the emotional, psychosocial, and physical impact of swallowing difficulties on an individual's life. Self-report is the best method to assess the impact of swallowing on daily living (Cella and Stone, 2015). This can be achieved by patient interviews; however, interviews are rarely systematic and may be difficult to conduct and repeat owing to time constraints. Additionally, repeatedly conducting verbal interviews may be onerous for patients with HNC as oral and other physical symptoms experienced because of treatment may impede speech. In chapter 3, patients reported the communication problems caused by impaired voice production, oral pain and fatigue, such symptoms are also reported elsewhere in literature (Zebralla et al., 2021). Self-report is also achieved through a validated and reliable HNC dysphagia questionnaire to quantify severity, monitor changes over time – including treatment response – and to detect health changes that are important from the patients'

perspective (Rogers, 2010). A questionnaire can also be used as a means of capturing and summarising data for a large group of patients.

A PRO measure is defined as 'any report of the status of the patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else' (U.S. Department of Health, 2006). Using PRO measures, swallowing was selected as a top priority pre-treatment for 36% of HNC patients treated with (Chemo)radiotherapy (CRT) increasing to 48% post treatment (Wilson, Carding and Patterson, 2011) and persisting up to six years post treatment (Patterson et al., 2018). Moreover, swallowing-related impairments of considerable concern were noted by patients up to one year post treatment following Intensity Modulated CRT in the swallowing-related domains (saliva [54%], taste [28%] and chewing [23%]) (Roe et al., 2014).

Surgically treated patients also report swallowing difficulties. A cross-sectional study of patients with tongue cancer one year postoperatively found that 35% reported taking a longer time to eat, 28% had chewing difficulties and 21% complained of food sticking in the mouth (Costa Bandeira et al., 2008). Over 60% of patients had significantly impaired swallowing two years postoperatively (Lahtinen et al., 2018).

4.1.1 Health-related quality of life and patient-reported outcomes for dysphagia

Health-related quality of life (HRQOL) is a specific subset of QOL, although some use the terms interchangeably. HRQOL encompasses symptoms, treatment side effects and functional status (Rogers, Fisher and Woolgar, 1999; Chandu et al., 2006). Typically, HRQOL is assessed by patient self-report using PRO measures (Rogers, 2010). Most HNC-specific PRO measures include swallowing-related domains. These domains are, however, limited in the number of component dysphagia questions and are not the principal focus of the questionnaires. A systematic review identified 57 HNC-specific PRO measures to assess HRQOL in physical functioning, psychosocial functioning, and treatment regret among more than 700 HNC HRQOL studies (Ojo et al., 2012). The main items contributing to swallowing related QOL were odynophagia, mouth opening, xerostomia/sticky saliva, sensation, and social eating. One example of a commonly used cancer PRO that includes swallowing-related questions is the European Organisation for Research and Treatment of Cancer Questionnaire and its supplementary module, which is specifically designed for HNC

(EORTC-HN35). The EORTC-HN35 have 14 questions out of 35 questions about or related to swallowing (Aaronson et al., 1993; Bjordal et al., 1999). This module, the EORTC-HN35, has been updated to become HN34 (qol.EORTC.org, D.A, 2021). However, the EORTC-HN35 needs to be used in conjunction with the EORTC-QLQ-30, making the total number of questionnaire items 65.

Patient-reported outcome measures for dysphagia

A small number of dysphagia-specific PRO measures are specifically designed to assess swallowing-related outcomes. The selection of an appropriate measure should be based on sound psychometric properties, such as reliability, validity, responsiveness, scoring and burden (Patel et al., 2017).

Reliability

Reliability refers to 'the degree to which scores are free from random measure error' (Patel et al., 2017). It is often assessed by internal consistency and test–retest reliability. Internal consistency is an important measure of scale reliability; it signifies whether the scale items are homogeneous and whether they measure the same construct. The optimal method for assessing internal consistency is the Cronbach's alpha (De Vet et al., 2011). The reproducibility of the scale, also known as test–retest reliability, denotes the degree to which repeated measures in individuals who are in a stable state provide comparable results (Terwee et al., 2007). It is recommended to use the reliability coefficient (intra-class correlation coefficient [ICC]) as a testing parameter rather than the Pearson's correlation coefficient (r) as the latter does not take systematic errors into account while ICC takes into account the rater bias (De vet et al., 2011; Liu et al., 2016).

Validity

The aim of validity testing is to ensure that the instrument is reflective of what it proposes to measure (De Vet et al., 2011). Criterion validity is the degree to which an instrument reflects a 'gold standard'. Achieving this type of validation is not always possible as gold-standard instruments may not be available. An alternative, construct validity, tests the hypothesis that a certain relationship exists between the instrument under study and another existing valid instrument with similar or dissimilar constructs. When an instrument is translated, it is important to test its cross-cultural validity. This typically starts with an accurate translation and adaptation process, which will be elaborated upon in section

4.1.2. Responsiveness is a further measure of validity, and it refers to the ability of the PRO measure to detect changes over time (Patel et al., 2017). Responsiveness can only be assessed longitudinally.

Scoring and burden

All measures should provide instructions on how to process missing responses and to avoid bias resulting from missing data (Patel et al., 2017). It is also important that the measure does not cause patient and clinician burden. Burden can be caused by the amount of time and effort required to complete, score and interpret the results of the PRO measure. A summary of these properties in addition to some psychometric terms is provided in Table 18.

Table 18 A glossary of psychometric terms

Concept	Term	Definition
Reliability	Cronbach's alpha	A measure of the reliability of a composite rating scale (Pereira-Maxwell, 1998). It is an index of internal consistency of a test ranging from 0 to 1.
	Test-retest reliability	A measure of the reproducibility of the scale (Patel et al., 2017).
	Intraclass correlation	The proportion of variance of an observation due to between-subject variability in the 'true' scores of a measuring instrument (Everitt, 2009).
Interpretability	Floor or ceiling effect	A term used to describe the condition where many respondents have scores that are at or near the possible lowest or the highest possible scores (Everitt, 1995).
Validity	Criterion validity	The degree to which the scores of a measurement instrument are an adequate reflection of a 'gold standard'
	Construct validity	The degree to which the scores of a measurement instrument are consistent with hypotheses.
	Cross-cultural validity	The degree to which the performance of the items in a translated or culturally adapted PROM are an adequate reflection of the performance of items in the original version of the instrument. This starts with an accurate translation process.
	Responsiveness	The ability to detect changes over-time. This is a form of validity testing and requires a longitudinal study to confirm the results (De Vet et al., 2011).
Associations	Correlation coefficient	An index that quantifies the linear relationship between a pair of variables. Various correlation coefficients are available, all taking values between -1 and 1, with the extreme values indicating a perfect linear relationship and the sign indicating the direction of the relationship (Everitt, 2009).

In the rest of this subsection, I will describe the most commonly used and reported dysphagia-specific PRO measures. The MD Anderson Dysphagia Inventory (**MDADI;** Chen et al., 2001) is one of the most used instruments, and it has been specifically developed for patients with HNC. The MDADI was developed through focus groups consisting of healthcare professionals with experience of working with HNC patients (i.e., head and neck surgeons and speech and language therapists [SLT]), however, not many of them experienced dysphagia themselves. Following that, focus groups of HNC patients were conducted to obtain information on their experiences with dysphagia in order to finalise the instrument. The MDADI comprises 20 items, which are divided into four main domains; the global domain (one item) asks about the overall impact of dysphagia on daily routine, the emotional domain (six items) assesses a patient's emotional response to dysphagia, the physical domain (eight items) represents self-perceptions and the physical manifestations of dysphagia and the functional domain (five items) captures the impact of dysphagia on a patient's daily activities.

The MDADI was validated on 100 HNC patients and showed good internal consistency and reproducibility as determined by test–retest reliability. Moreover, it was deemed valid in terms of content and known-group validity (Chen, et al., 2001). Its psychometric properties, however, are understudied, and it does not include a strategy for missing data (Petal et al., 2017), in addition, the MDADI domains were selected by the developers and were not fully tested. The MDADI also showed responsiveness to changes from baseline status up to one year (Wilson et al., 2011); however, a study showed that at six years post treatment, there were no statistically significant differences from the one year post treatment data (Patterson et al., 2018). Nevertheless, it is difficult to interpret what these non-significant differences signify without reference to the expected trajectory according to another metric.

We conducted a study to further assess the psychometric properties of the MDADI by performing factor analysis to investigate item redundancy (Lin et al., 2021). We found through different statistical analyses that the MDADI in fact contained a single factor. The items loading to the factor were: two items in the emotional subscale, two items in the functional subscale, and one item in the physical subscale. This suggests that the MDADI could be shortened to five questions instead of 20 questions. However, these results should be interpreted cautiously because further testing is required to ensure that the shortened

MDADI, or the 'MiniDADI' as suggested, is a valid and reliable instrument (Lin et al., 2021). Appendix F.

I decided to include the MDADI in the Swallowing Outcome Package on the basis of its proven reliability and validity, and its wide use in research and clinical practice in addition to ensure the patient perspective was captured in the Swallowing Outcomes Package. In research, the MDADI is used as a primary or secondary endpoint for randomised clinical trials. The MDADI is also used as a gold standard to validate new swallowing scales. Moreover, many studies have used the MDADI to compare interventions, site of tumour and responsiveness to changes over time (see Table 19). The MDADI requires 10–15 min to complete, making it less burdensome than other PRO measures used in clinical practice.

Recently, a study found that the between-group minimally clinical important difference (MCID) for the total MDADI score is 10 points (Hutcheson et al., 2015). The MCID is defined as the smallest change in outcomes that patients perceive as significant or important (Copay et al., 2007). The identification of this difference enhances its clinical and research utility as it allows for clinically meaningful comparisons between treatment groups.

The MDADI has been translated over a dozen times, including 10 published versions (Bauer et al., 2010; Carlsson et al., 2011; Guedes et al., 2012; Hajdú et al., 2017; Kwon, Kim et al., 2013; Matsuda et al., 2018; Montes-Jovellar et al., 2018; Schindler et al., 2008; Speyer et al., 2011; Yee et al., 2020), reflecting its extensive use worldwide and its utility as an outcome measure in international trials.

Table 19 The use of the MDADI instrument in research

Used in/for	Brief details
Clinical trials	-PATHOS: Determine if reducing the intensity of adjuvant treatment after TORS will result in better long-term swallowing with maintained excellent survival outcomes for patients with HPV+ oropharyngeal cancers (Owadally et al., 2015). -DARS: Determine if dysphagia-optimised intensity modulated radiotherapy will improve long-term swallowing function without impacting survival outcomes (Petkar et al., 2016). -ORATOR: Comparing one-year post treatment swallowing QOL in patients with oropharyngeal cancer between patients who received TORS with neck dissection and patients receiving (C)RT (Nichols et al., 2019). -SwallowIt: A randomised trial comparing three service delivery models for prophylactic swallowing exercises during (C)RT (Wall et al., 2020). -BEST OF: Assess and compare MDADI scores in oropharyngeal, supraglottic and hypopharyngeal cancer patients who receive either IMRT or TORS (Simon et al., 2018)
New scales validation	-DIGEST: A tool developed to measure the pharyngeal stage of swallowing (Hutcheson et al., 2017).
Determining the feasibility and utility of interventions	-Investigating the effectiveness of pre-treatment swallowing exercises on post-treatment QOL (Kulbersh et al., 2006). -Assessing the efficacy of acupuncture on swallowing-related QOL (Lu et al., 2012). -Evaluating the feasibility of a cognitive behavioural swallowing therapy (Patterson et al., 2018). -Evaluating the effectiveness of electrical stimulation on swallowing post-treatment (Ryu et al., 2009). -Assessing the feasibility of a swallowing exercise package (Wells et al., 2016).
Comparison between different treatment modalities or reporting on specific HNC tumour sites	-Investigating swallowing outcomes for different advanced laryngeal cancer treatments (Burnip et al., 2013).

	-Comparing the change in swallowing outcomes for patients with advanced oropharyngeal cancer between transoral laser microsurgery ± adjuvant treatment and CRT treatments (O'Hara et al., 2015). -Evaluating functional outcomes after transoral robotic surgery (Iseli et al., 2009; Boudreaux et al., 2009).
Longitudinal studies	-Reporting swallowing function in patients with oropharyngeal cancer (Goepfert et al., 2016; Goepfert et al., 2017). -Assessing swallowing trajectory following HNC (Patterson et al., 2018; Roe et al., 2014).

Abbreviations: PATHOS: Post-operative adjuvant treatment for HPV-positive tumours. DARS: Dysphagia/Aspiration at risk structures. ORATOR: Oropharynx: radiotherapy vs. trans-oral robotic surgery. DIGEST: Dynamic imaging grade of swallowing toxicity.

Another PRO measure is the **Dysphagia Handicap Index (DHI;** Silbergleit et al., 2012), which was developed in English in the United States. The questionnaire items were based on dysphagia complaints made by patients with swallowing difficulties as a result of different medical diagnoses. The final version of the scale was validated on 214 patients with dysphagia from different aetiologies, with 36% (n = 76) of them being patients with HNC. Similar to the MDADI, this 25-item self-administered questionnaire has three subscales – functional (nine items), physical (nine items) and emotional (seven items) – and one additional general question which concerns the overall impression of swallowing difficulty. A systematic literature review suggests that the DHI has strong psychometric properties in terms of validity and reliability (Timmerman et al., 2014). Although this instrument has gained popularity in recent years (Sobol, Kober and Sielska-Badurek, 2021), its use in HNC-related studies is limited. The DHI has been validated in different languages, for example, Arabic, (A-DHI; Farahat et al., 2014), Japanese (Oda et al., 2017), Hebrew (Shapira-Galitz et al., 2019), Kannada (Krishnamurthy and Balasubramanium, 2020) and Persian (Barzegar Bafrooei et al., 2020).

The Swallowing Quality-of-Life Questionnaire **(SWAL-QOL;** McHorney, et al., 2002) is a 44-item scale designed to assess dysphagia from a patient's perspective in dysphagia of different aetiologies. The scale assesses swallowing QOL in 10 domains: food selection, burden, mental health, social functioning, fear, eating duration, eating desire, communication, sleep and fatigue. The instrument generates two metrics scaled from 0 (no

problems) to 100 (signifying maximum problems); one indicates total symptoms, whereas the other is the overall SWAL-QOL score (McHorney et al., 2002). A study using a Dutch SWAL-QOL version (Rinkel et al., 2009) suggested that an overall total score of >14 indicates a need for further swallowing assessment. The SWAL-QOL has excellent reliability and validity and therefore is a candidate for HNC clinical research and practice. However, responsiveness – an important metric – was not studied in the original version of the SWAL-QOL. In the Italian version of the instrument, the SWAL-QOL was deemed responsive in neurological patients in the short term (two months; Ginocchio et al., 2016). Nonetheless, its high number of items (44) could limit its application, as it may be burdensome for the patients to complete and unwieldy to score. A research team in Kuwait are working on an Arabic version of the scale (Alshammari et al., 2019).

The Eating Assessment Tool (**EAT-10;** Belafsky et al., 2008) includes a short list of 10 symptoms that can be used for a general dysphagia population (Belafsky et al., 2008). It is suggested that the EAT-10 has item redundancy, confirmed by its high internal consistency ($\alpha = 0.95$), and factor analysis, implicating just one single underlying construct (Sinn et al., 2020). Each item is rated on a Likert scale from 0 (indicating no problems) to 4 (indicating severe problems), with a simple arithmetic total score. The EAT-10 was found to be reliable and valid but not responsive to changes over time (from pre-treatment until discharge from speech and language therapy sessions – the numeric duration was not reported; Sinn et al., 2020). In general, the EAT-10 is a very simple and easy-to-score tool, which may reduce the burden on both the patients and the healthcare professional; however, it requires further psychometric testing to ensure that it provides valid and sound results. It is also important to mention that the EAT-10 is a tool that measures physical symptoms and does not report on the impact of these symptoms.

The Swallowing Outcomes After Laryngectomy (**SOAL**) questionnaire (Govender et al., 2012; Govender et al., 2015) was developed for patients with laryngectomy. Its 17 symptom questions address unique swallowing problems encountered after a laryngectomy. Scores range from 0 to 34, with lower scores reflecting fewer self-reported swallowing problems (Govender et al., 2015). Test–retest reliability was established for the SOAL but in only a small sample of patients, and it was not validated against other valid measures. SOAL is highly specific to patients with laryngectomy, thus limiting comparisons

of treatments; another limitation of the questionnaire is that questions with missing responses are considered invalid (Petal et al., 2017).

The 17 –item Sydney Swallowing Questionnaire **(SSQ;** Wallace, Middleton and Cook, 2000**)**, was validated in patients with neurological disorders and subsequently in patients with HNC (Dwivedi et al., 2010). Items are scored on a 100 mm visual analogue scale, and higher scores indicate more problems. The SSQ shows acceptable reliability, in terms of internal consistency (Cronbach's $\alpha = 0.95$) and test–retest reliability (rho = 0.83 for the total SSQ score, 0.7 for the general score). The questionnaire is also valid when compared against the MDADI. Table 20 provides a summary of all these PRO measures and their psychometric properties.

Table 20 Summary of commonly used patient-reported swallowing outcome measures

Questionnaire/ Scale	Language	Study population	Total n and HNC (%)	Setting	Psychometric properties
DHI	English	Patients with dysphagia	-Preliminary version n = 77 (HNC = 10 (13%)). -Final version n = 214 (HNC = 76 (36%)) -Controls n = 74 -Test-retest n = 63	Henry Ford Hospital, USA	-Reliability: Cronbach α: Total score = 0.94 Subscales 0.78 – 0.91 Test-retest ICC: (0.75 – 0.86) -Validity: Criterion and known-group validity.
	Arabic	Patients with dysphagia	-n = 94 pts -Controls n = 162 -Test-retest n = 22 patients	King Khalid University Hospital, Saudi Arabia	-Reliability: Cronbach α: Total score: 0.94 Subscales: 0.88 – 0.89 Test-retest ICC: (0.79 – 0.96) -Validity: Content and known group
SWAL-QOL	English	Patients with dysphagia	-n = 386 pts (cancer n = 109 (28%)) -Controls n = 40	Different centres/hospitals, USA	-Reliability: Cronbach α: 0.79 - 0.95 Test-retest ICC = 0.59 to 0.91 -Validity: Convergent, discriminant and known-group validity
	Arabic	Patients with Parkinson's dysphagia	NA	NA	Unpublished
EAT-10	English	Patients with voice and swallowing disorders	-n = 235 pts (HNC n = 42 (18%)).	-Outpatient swallowing and voice clinics, USA	-Reliability: Cronbach α = 0.96 Internal consistency ICC = 0.72 – 0.91 -Validity: Criterion validity

	Arabic (based on abstract)	Patients with oropharyngeal dysphagia	-n= 138 pts -controls = 83	NA	-Reliability: Cronbach α = 0.92 Internal consistency ICC = 0.73 -Validity: Known-group validity
SSQ	English	Patients with HNC	-n = 54 -test-retest n = 31	Outpatient clinic, UK	-Reliability: Cronbach α = 0.95 Internal consistency rho = 0.71 – 0.83 -Validity: Content and construct validity
SOAL	English	Patients with laryngectomy	-n = 110 pts -test-retest n = 15	Four National Health Service hospitals, United Kingdom	-Reliability: Cronbach α = 0.91 Internal consistency ICC = 0.73 -Validity: Construct and known-group validity
MDADI	English	Patients with HNC	-n = 100	MD Anderson Cancer Centre, USA	-Reliability: Cronbach α = 0.96 Internal consistency ICC = 0.69 – 0.88 -Validity: -Criterion, construct and known-group validity

4.1.2 Adaptations of patient-reported outcome measures

Where possible, the use of existing validated instruments rather that developing new instruments is recommended (Penson, Litwin and Aaronson, 2003). There are several advantages to having an instrument translated and culturally adapted rather than generating a new one. First and foremost, using an existing instrument is more efficient, saving time and resources (De Vet et al., 2011; Guillemin, Bombardier and Beaton, 1993). This could lead to improving patients' pathway faster. Additionally, a translated version of a commonly used PRO measure allows for comparisons in multinational and multicultural research projects. It also facilitates equality and inclusion in a multicultural society, such as that in Kuwait, by including both the English and Arabic versions in the clinical setting.

A systematic, multi-step approach is required to achieve an effective instrument translation and adaptation (Acquadro et al., 2008). There are several available translation guidelines. The American Association of Orthopaedic Surgeons (AAOS; Beaton et al., 2000) propose six stages for translation and cultural adaptation; these stages are summarised as follows:

1- Translation: It is recommended to have at least two forward translators whose mother tongue is the targeted language (in this study: Arabic). One of the translators should be informed of the concepts being explored. Their translation is intended to provide a clinical perspective. The second, naïve translator offers a translation in a colloquial terminology.
2- Synthesis: A recording observer and the two translators synthesize the two translations, working with the original questionnaire as well. They produce a T3 version, via consensus, with a written report documenting the synthesis process.
3- Back translation: Using the T3 version, and while being completely blind to the original version, two back translators whose mother tongue is the source language (English) and who are fluent in the targeted language (Arabic) produce two separate translations. The aim of the step is to check whether the translated version reflects the original version.
4- Expert committee review: In collaboration with the questionnaire developer, the cross-cultural equivalence is assessed by language experts, health professionals, the translators and the back translators.
5- Pretesting: This is a key stage. In this stage, participants are recruited to test the questionnaire and are probed by the investigator to assess the understandability of

an item. Usually through cognitive debriefing verbal information is collected about the instrument responses and is used to determine whether the question is understood as intended (Beatty and Willis, 2007). Two general paradigms are used: the probing-centred paradigm – where the participants are encouraged and probed to provide information based on their responses – and the think-aloud paradigm – where the participants generate ideas based on their thinking without the intervention of the interviewer (Willis, 2005).

6- Submission and appraisal of the reports by the developer: All the reports should be submitted to the developer to verify that the recommended guidelines were followed and that the reports reflect the process.

After completing these steps, the translated instrument must undergo further testing to ensure that it demonstrates sound psychometric properties, such as reliability, validity and responsiveness, as described earlier.

4.2 Rationale and Aim

In Kuwait, no measures are currently used to assess dysphagia-specific QOL in HNC. Incorporating an easy and short measure would be beneficial, as patients can complete it while waiting to be called in to see their doctor. A valid and reliable instrument is essential to quantify dysphagia severity and monitor changes over time – including treatment response – and to detect health changes that are important from the patients' perspective. Therefore, the aim of this study is to create and evaluate an Arabic version of the MD Anderson Dysphagia Inventory (A-MDADI) to be used as a part of the Swallowing Outcome Package. I also aim to evaluate the psychometrics properties of the 5-item version of the MDADI (A-MiniDADI) as suggested by our findings (Lin et al., 2021). This will be explored in the similar manner of the longer original version.

4.3 Materials and methods

4.3.1 Protocol

Ethical approval

Ethical approval was obtained from Newcastle University and the Research and Ethics Committee at the Ministry of Health – Kuwait. Mid-study an ethics amendment was submitted to allow for online questionnaires and to identify patients and contact them by

phone in order to increase recruitment. Ethics application no: 1441_1/2025/2018 (See Appedix G) for Newcastle University ethical approval).

Cross-cultural translation and adaptation

The official guidelines recommended by the AAOS (Beaton, et al., 2000) were followed. The adaptation process went through the six recommended stages to assure that the adapted MDADI version is equivalent to the original one. Figure 9 summarises the whole translation and adaptation process. Below is a detailed description of the process:

1- **Initial translation stage:** To achieve this stage, two translators were asked to translate the MDADI into Arabic. They were asked to produce a report alongside their translation including any challenges they faced during the process, and their rationale if they decided to change any of the phrases or the response options. An informed translator, a speech and language therapist (SLT), produced the first translated version (T1). The second translator, who is a qualified translator with no clinical background, produced a (T2) version. Both translators submitted a written report with their comments, underlining challenging phrases and reservations.

2- **Synthesis of the original, T1 and T2 versions:** Through a tele-meeting, the two translators and the researcher (myself) compared the translations with the original version to reach consensus regarding the discrepancies and differences in order to produce a common translation (T3).

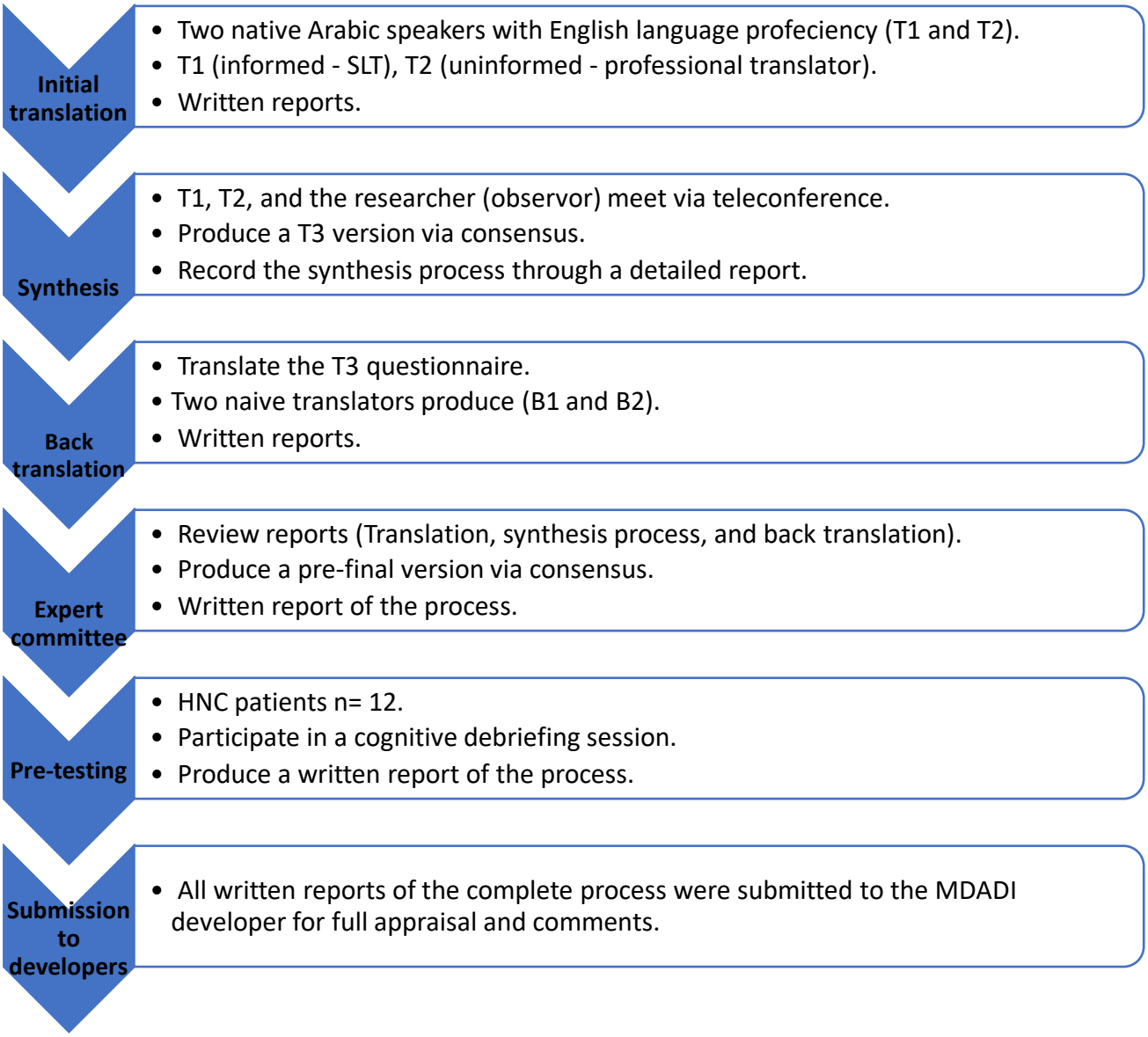
3- **Back translation:** For this stage, two 'naïve' translators, with no clinical background or prior knowledge of swallowing disorders, conducted a back-translation from the T3 version into English. Both versions were submitted with one back-translator submitting comments concerning the difficulties encountered.

4- **Expert committee review:** All translations were scrutinised to assure that they are comparable. The T3 version was sent to an Arabic language undergraduate student to provide feedback on the language used in the final version. Moreover, the reports were sent to the original MDADI developer, Dr Chen, who agreed to proceed with testing the pre-final version.

5- **Pre-testing:** Arabic speaking HNC patients were recruited and asked to fill-out the A-MDADI and to participate in a cognitive debriefing to evaluate the new questionnaire. To reduce stress on participants and to take control over the interview, the 'probing-centred paradigm' was applied (Willis, 2005). The verbal probing technique relies on a series of questions posed by the researcher regarding the instrument being used. Using the four-stage cognitive model suggested by Tourangeau (1984; comprehension, retrieval, judgement, and response), the interview topic-guide was adapted from Schildmann et al., 2015. Participants were asked about their opinion regarding the questionnaire in general, the language used, and if they would suggest adding any more questions. The whole process, and suggestions made by the participants were documented in a report. See Appendix H.

6- **Submission to the developer:** All documents were sent to the original MDADI developer – Dr Amy Chen, who approved and gave permission to continue with the validation process.

Figure 9 Summary of the MDADI translation and adaptation process

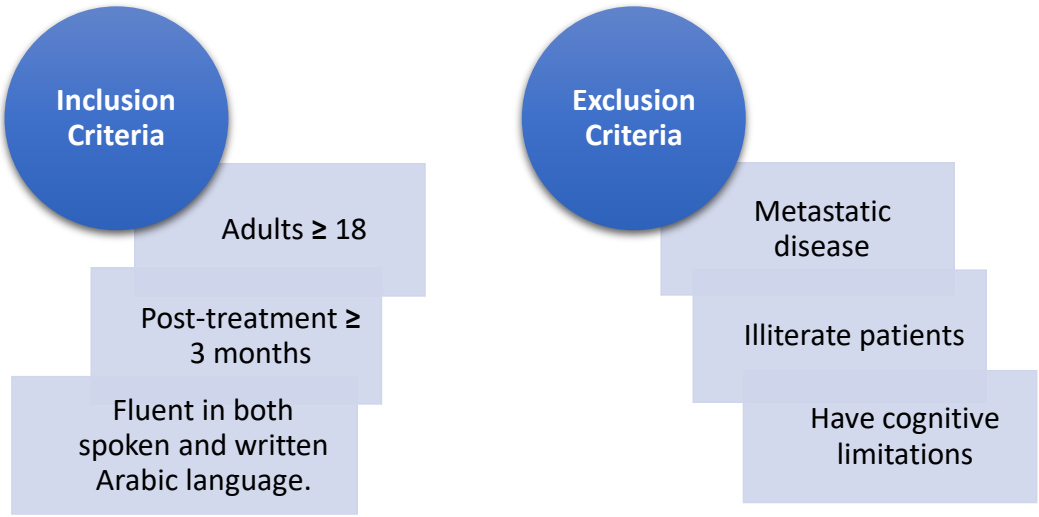


Participants and data collection

Consecutive Arabic speaking patients with HNC who agreed to participate were recruited during out-patient visits to the head and neck oncology department at the Kuwait Cancer Control Centre (KCCC), from February 2018 – July 2018. Inclusion and exclusion criteria are shown in Figure 10. Recruitment was independent of the presence or absence of dysphagia. This allowed incorporation of all patient groups. Participants had to be at three-months or more post-treatment, this period was selected as swallowing shows the greatest deterioration with no significant changes up to one-year post treatment (Wilson et al., 2011), allowing stability for test-retest testing. For the pre-testing part of the translation process (Step #5 in section 4.3.1; Figure 9) before finalising the A-MDADI version, all

participants who agreed to participate were recruited regardless of their treatment status. All participants were given a patient information sheet and signed a consent form (see Appendix I).

Figure 10 Inclusion and exclusion criteria



Psychometric validation

Reliability

Reliability was verified by testing for internal consistency and test-retest reliability. Participants were asked to score the MDADI twice, the first time (test; MDADI1), and the second time (retest; MDADI2).

Validity

Assessing criterion validity was not possible as there is no 'gold-standard' instrument available to assess QOL in HNC population. Cross-cultural validity was established by following the suggested guidelines in Figure 9. Finally, to assess construct validity, my hypothesis was that the A-MDADI total and subscale scores should have a negative correlation with the A-DHI total score and subscales, and a negative correlation with the A-EORTC-HN35 since high MDADI scores indicate better QOL, whereas high DHI and EORTC-HN35 scores indicate poorer QOL. The DHI and the EORTC-HN35 questionnaires were chosen for validity testing because both are available and validated in the Arabic language.

Moreover, for cross-validation, a further validity analysis was conducted on a different set of data that were available from participants who completed the English versions of the MDADI and the EORTC-HN35 (Patterson et al., 2018).

Scoring

EORTC-QLQ30 and EORTC-HN35

The European Organisation for Research and Treatment of Cancer Questionnaire **(EORTC QLQ-C30)** is a general quality of life instrument for cancer patients. It consists of a global scale, five functional sub-scales, and nine symptom-specific subscales. It also has an HNC-specific supplementary module, the **EORTC-HN35** (now HN-34; 2021) (Bjordal et al., 1999). The EORTC-QLQ30 has three domains: global health status (QOL), functional scales, and symptom scales. The EORTC-HN35 is a symptom scale, with 14 items relevant to eating: swallowing (4 items), sensory problems (taste, smell; 2 items), social eating (4 items), teeth (1 item), mouth opening (1 item), dry mouth (1 items), and sticky saliva (1 item).

For the EORTC-QLQ-C30, high scores for the functional domains represent good function and QOL. For the HN-35 high symptom scores equate to worse QOL. For both scales (EORTCQLQ-C30 and HN-35), there are four possible answers for each item: not at all (scored 1), a little (scored 2), quite a bit (scored 3), and very much (scored 4) with possible range of scores from 0 – 100.

The scoring of the EORTC instruments is complicated. For both scales, first the raw score is calculated by this equation: *Raw Score = RS = $(I_1 + I_2 + \ldots + I_n)/n$.* A linear transformation then standardises the raw score to range from 0 to 100. For functional scales the equation is: *Score = {1-(RS – 1)/range} x 100.* Symptom and QOL scales are transformed by this equation: *Score = {(RS - 1)/range} x 100*. The EORTC-HN35 is scored using the symptoms/QOL equation.

**N. B: Raw scores = the average of the items that contribute to the scale, I = item, n = number of items, range = the difference between the maximum and the minimum possible value of the raw score.*

DHI

For the DHI, there are four possible outputs: a total score (25 items), an emotional score (seven items), a functional score (nine items) and a physical score (nine items). There are three possible answers for each question: never (scored 0), sometimes (scored 2), and always (scored 4), making the possible range of score from 0 – 100 (better QOL – decreased QOL, respectively). The additional general question is scored from 1 (normal) to 7 (severe difficulty).

The MDADI

The MDADI is a Likert questionnaire with five possible responses (strongly agree, agree, no opinion, disagree, strongly disagree - scored 1 to 5). All but two items (E7: 'I do not feel self-conscious when I eat' and F2: 'I feel free to go out to eat with my friends, neighbours, and relatives') are worded such that high scores indicate better QOL. To score the MDADI, the mean score of each domain is calculated and then multiplied by 20 to get the scores for the composite, emotional, functional, and physical domains, with a possible range of 20 – 100, where 20 indicates a low functioning (worse QOL), and 100 signifies high functioning (better QOL). The global domain is scored individually, with the same possible range of scores and characteristics of the composite MDADI (see Appendix J for the translated and original MDADIs).

4.3.2 Statistical analysis

The data were entered into Microsoft Excel spreadsheet. All analyses were conducted using the IBM SPSS statistics for Windows, version 24. Descriptive statistics were obtained for age, sex, tumour site, T, N stages, treatment type, smoking and feeding status. The mean time (months) from treatment to study entry was also measured.

To investigate internal consistency, Cronbach alpha (α) was calculated on the MDADI composite score and emotional, functional, and physical domains. The test was performed on the results of MDADI1, and the lowest acceptable value was 0.7 (De Vet et al., 2011). Floor and ceiling effects were also reported as percentages and were considered if 15% of the patients scored any of the extreme scores (20 – 100) in any of the domains (De Vet *et al*, 2011). Similarly, Cronbach alpha (α) and floor and ceiling effects were calculated on the 5-items suggested for the MiniDADI (Lin et al., 2021).

The intra-class correlation coefficient (ICC) was calculated by a two-way random analysis for absolute agreement on test-retest (MDADI1-MDADI2, respectively) scores. ICC was also calculated for the MiniDADI1-MiniDADI2 scores. The results of the ICC are presented with a 95% confidence interval (CI). ICC values less than 0.5 are considered poor, values between 0.5 and 0.75 were considered acceptable, good if > 0.75 and excellent if > 0.9 (Koo and Li, 2016).

To test the suggested hypothesis for construct validity (i.e., the MDADI total score and subscale scores will have a negative correlation with the DHI total score and subscales, and

a negative correlation with the EORTC-HN35), I used Spearman's Rho test. The test was performed to investigate the correlation between the MDADI1 domains (composite, global, function, emotional and physical) with the other comparable scores of the DHI and EORTC-HN35 domains. Correspondingly, I investigated the correlation between the MiniDADI with the DHI total score, and the EORTC-HN35 swallowing-related domains. Correlation coefficient values > 0.19 are considered very weak, 0.2 – 0.39 weak, 0.4 – 0.59 moderate, 0.6 – 0.79 strong, and 0.8 – 1 are very strong correlations (Cohen, 2013).

4.4 Results

4.4.1 Translation and cultural adaptation

This section reports on the cross-cultural translation and adaptation process following the recommended guidelines (Figure 9).

Translation and adaptation results

In **stage two (synthesis)** of the translation and adaptation process, it was agreed between the two translators to make some alterations to the term 'swallowing', items E7, E4, E6, P4 and F4, and the response option 'no opinion'. Regarding the term 'swallowing', it was decided to change it to 'eating, drinking and swallowing'. As the word swallowing can be conceived as the exact moment of deglutition (pharyngeal phase), this would eliminate the oral stage. Although, 'eating, drinking and swallowing' was mentioned in the questionnaire introduction, it was also reiterated throughout the whole questionnaire in case the patients skip reading the introduction. In addition, the word 'self-conscious' in statement **E7 'I do not feel self-conscious when I eat'** was translated into 'anxious' (Table 21). It was decided that the word 'anxious' would be easier to understand in Arabic. Moreover, the word 'upset' in statement **E4 'I am upset by my swallowing problem'** was perceived to be ambiguous in Arabic, and it was translated into 'discontent' to indicate sadness and irritation. Additionally, in statement **E6 'I have low self-esteem because of my swallowing problem'** the word 'confidence' was added beside the term 'self-esteem', to provide more elaboration and to add a little distraction from the term 'self-esteem', as the term itself may be perceived as a strong language in Arabic (self-regard). In statement **P4 'I feel that I am swallowing a huge amount of food'** the word 'mouthful' was used instead of 'swallowing a huge amount of food' as the latter may be confusing and is often used for body shaming. Additionally, in statement **F4 'I feel excluded because of my eating habits'** the term 'exclusion' has a very powerful, active connotations in Arabic, thus, it was

translated into ‘isolation’. Finally, the response category ‘no opinion’ was changed into ‘don’t know’ as this is how it is commonly used in other Arabic questionnaires. These changes were finalised after the cognitive debriefing results, which can be seen below in Table 21.

Table 21 Summary of changed items in Arabic-MDADI

Item number/location	Original	Translated	Rationale
Intro and throughout the while questionnaire	Swallowing	Eating, drinking and swallowing	To indicate the oral phase in addition to the pharyngeal phase
E7	Self-conscious	Anxious	Easier to understand in Arabic
E4	Upset	Discontent	The term upset is strong in Arabic
E6	Self-esteem	The term confidence was added	-New concept -Strong term
P4	Swallowing a huge amount of food	Mouthful	-Confusing -Body shaming
F4	Exclusion	Isolation	Strong term
Response choices	No opinion	Don’t know	Used in other Arabic questionnaire

Pre-final Testing Participants’ Demographics

Prior to pre-final testing, two back translators performed two separate translations, and after ensuring that all outcomes were comparable, the reports were sent to Dr Chen, who was happy to continue to field testing. For the pre-final testing (Stage 5) n = 12 HNC patients participated (6 males and 6 females, Table 22). The mean age was 49 years with varied HNC sites. All participants were consuming food orally. The interval since last treatment ranged from 0 to 96 months.

In stage five, patients who participated in the cognitive debriefing gave their feedback on the questionnaire immediately after its completion. In general, participants thought that the questionnaire was easy, direct, and very relatable. None of them thought that it was

offensive, or embarrassing. They also appreciated why certain terms had been changed. Two respondents criticised the response options, thinking that they were confusing and should be reduced to 'always, sometimes, never'. Conversely, other participants agreed that they could map their experiences to the proffered response choices. Regarding the response options: 'strongly agree', 'agree', 'no opinion', 'disagree' and 'strongly disagree', participants' thought that changing 'no opinion' to 'I don't know' would be preferable, since it concerns their own personal experience, they must have an opinion. The option 'I don't know' was mostly used in response to statements **F1 and E3**, **'other people find it difficult to cook for me'**, **'others are irritated by my eating habits'**, respectively. Five out of the 12 participants did not notice that statement E7 was scored in reverse **E7 'I do not feel self-conscious when I eat'**, in comparison to only two in statement **F2 'I feel free to go out to eat with my friends, neighbours and relatives'**. The reason is that in question E7, the negation could be confusing to participants, compared with question F2, which is a direct question. However, these two statements were not changed to match the rest of the instrument (were not unified). Most participants admitted that they did not read the introductory briefing, which gave rise to some confusion when answering the questionnaire as some became confused and responded with reference to past experiences. As a result, the statement **'last week'** was made bold and underlined to highlight the questionnaire response time frame to patients.

Table 22 Demographics of patients participating in the pre-testing of the MDADI (n = 12).

Patient characteristics	Category	N
Age (years)	Range	(22 – 72)
	Median	51
	Mean ± SD	49 ± 14
Sex	Male	6
	Female	6
Smoking status	No	7
	Ex	3
	Yes	2
Tumour site	Nasopharynx	5
	Larynx	3
	Oral	2
	Oropharynx	2
Treatment	(Chemo)radiotherapy	7
	Surgery and RT	2
	Surgery	2
	Missing information	1
Time since treatment to study entry (months)	Range	(0 – 96)
	Mean ± SD	23 ± 36

4.4.2 Psychometric validation of the A-MDADI

Participants

Fifty-five HNC patients agreed to participate, however one person was excluded as he did not complete any of the questionnaires. In total, therefore 54 HNC patients filled out the A-MDADI1, A-DHI, EORTC-QLQ30 and HN35, and 30 patients filled-out the MDADI2 for the test-retest analysis. Participants' age range was 23 – 75 with a mean of 50 years, and the majority were males (64%). Out of the 54 participants, n = 19 were more than 24 months post-treatment. Sociodemographic and clinical characteristics are presented in Table 23.

Table 23 Sociodemographic and clinical characteristics of n = 54 participants in the A-MDADI psychometric validation

Patient characteristics	Category	N (%)
Age (years)	Range	23-75
	Median	53
	Mean ± SD	50 ± 11
Sex	Male	34 (63)
	Female	20 (37)
Smoking status	Yes	4 (7)
	No	26 (48)
	Ex	24 (44)
Feeding status	Oral	53 (98)
	Tube feeding	1
Tumour site	Nasopharynx	19 (35)
	Larynx	17 (32)
	Oral	12 (22)
	Oropharynx	6 (11)
Tumour T stage	1	10 (19)
	2	20 (37)
	3	17 (32)
	4	5 (9)
	Missing	2
Tumour N stage	0	30 (56)
	1	11 (20)
	2	10 (19)
	3	1
	Missing information	2
Treatment	(Chemo)radiotherapy	31 (57)
	Surgery and (C)RT	15 (28)
	Surgery	6 (11)
	Missing information	2
Time since treatment to study entry (months)	Range	3 – 288
	Median	15
	Mean ± SD	45 ± 65
	Missing information	4

MDADI reliability

Internal consistency and interpretability

In some cases, it was obvious that the participant misinterpreted or did not notice the negation in statements E7: 'I do not feel self-conscious when I eat', and F2: 'I feel free to go out to eat with my friends, neighbours, and relatives', i.e., scoring high on the entire questionnaire, but low for the two items and vice versa. Responses were not reversed or adjusted as there are no guidelines specifically for this issue[*].

Internal consistency was assessed for all A-MDADI1 domains and the composite score. Cronbach α was the highest for the composite A-MDADI score (0.93), and the lowest for the functional subscale (0.72). Floor and ceiling effects were tested for all A-MDADI1 domains as well. Results reveal no floor effect for any of the domains, however, ceiling effects were found for the global and the functional domains. Table 24 summarizes the internal consistency results and floor and ceiling effects for all domains.

Table 24 Internal consistency and floor and ceiling effects (MDADI1) n = 54

MDADI domain	Items	Cronbach α	Mean (Range of scores)	Floor effect (%)	Ceiling effect (%)
Global	1	-	73 (20 – 100)	No (7%)	Yes (39%)
Physical	8	0.90	68 (28 – 100)	No (4%)	No (11%)
Emotional	6	0.82	77 (30 – 100)	No (4%)	No (9%)
Functional	5	0.72	79 (44 – 100)	No (4%)	Yes (20%)
Composite	19	0.93	75 (35 – 100)	No (2%)	No (2%)

Floor and ceiling effects are considered if 15% of the participants scored any of the extreme scores (20 – 100) in any of the domains

[*] For E7 statement 18 scores were misinterpreted (11 MDADI1, 7 MDADI2) and seven scores for the F2 statement (4 MDADI1, 3 MDADI2).

Test-retest reliability

Participants were asked to re-fill the A-MDADI (MDADI2) after at least one week to assess the test-retest reliability. The mean time between MDADI1 and MDADI2 was 16 days (range 8 – 32 days). In total, n = 30 participants were included in the test-rested reliability, two of the participants filled-out the online version of questionnaire. ICC values were obtained for all domains, and were acceptable, with the highest being 0.93 for the composite domain, and the lowest 0.82 for the global domain. Table 25 shows the results for the test-retest reliability.

Table 25 ICC values for test-retest reliability (MDADI1 and MDADI2 scores) *n = 30*

Domain	ICC [95% CI]
Composite	0.93 [0.87;0.96]
Emotional	0.92 [0.84;0.96]
Physical	0.89 [0.78;0.94]
Functional	0.87 [0.76;0.94]
Global	0.82 [0.61;0.91]

MDADI validity

Construct validity

Cross-cultural validity was established by strictly following the translation guidelines. As for the construct validity, the hypothesized negative relationship between the MDADI1 domains and the related domains of the DHI and the EORTC-HN35 was tested by Spearman's Rho test.

The A-MDADI composite domain had a very strong correlation (rho -0.85) with the A-DHI total, and the other domains (emotional, physical, and functional) correlated strongly with the related A-DHI domains. Table 26 below shows the correlation between the MDADI and DHI domains.

Table 26 Correlation between the MDADI score(s) and the DHI score(s) *n = 54*

MDADI Items	DHI domains	Correlation coefficient	*p* value	Correlation
Composite	Total	-0.85	*P <0.001*	Very strong
Emotional	Emotional	-0.67	*P <0.001*	Strong
Physical	Physical	-0.76	*P <0.001*	Strong
Functional	Functional	-0.69	*P <0.001*	Strong

Regarding the correlation between the A-MDADI and the A-EORTC-HN35, strong to weak correlations were found between the composite A-MDADI scores, and the swallowing-related domains in the A-EORTC-HN35. A strong correlation was found between the composite A-MDADI and the HN-Social Eating, and HN-Swallowing (-0.75 and -0.73, respectively). Correlation coefficients can be found in Table 27 below.

Table 27 Correlation between the MDADI composite score and the EORTC-HN35 domains n = 53

EORTC domains (# items)	Correlation coefficient	*p* value	Correlation with composite MDADI
HN-Social eating (4)	-0.75	*P <0.001*	Strong
HN-Swallowing (4)	-0.73	*P <0.001*	Strong
HN-Mouth opening (1)	-0.61	*P <0.001*	Moderate
HN-Senses (2)	-0.57	*P <0.001*	Moderate
HN-Dry mouth (1)	-0.50	*P <0.001*	Moderate
HN-Sticky saliva (1)	-0.35	*p* = 0.004	Weak
HN-Teeth (1)	-0.28	*P* = .029	Weak

Cross validation

For the purpose of cross-validation, an analysis was conducted on an available dataset of patients who completed both the English version of the MDADI and the EORTC-HN35. The results in Table 28 show correlations at three-months post-treatment. It should be noted that the sample size affects the size of the correlation.

Table 28 Correlations between the E-MDADI composite score and E-EORTC-HN35 n = 22

MDADI	EORTC domains	Correlation coefficient	*p* value	Correlation
MDADI composite	HN-Swallowing (n= 20)	-0.61	*P = 0.004*	Moderate
	HN-Senses (n = 22)	-0.65	*P = 0.001*	Moderate
	HN-Social eating (n = 22)	-0.58	*P = 0.005*	Moderate

Results of the A-MiniDADI

Reliability

Internal consistency Reliability

Assessment of the internal consistency of the five-items suggested for the 'MiniDADI': items (F4, E3, E6, F3 and P3) showed Cronbach α to be 0.89, well exceeding the lowest acceptable value of 0.7. Floor and ceiling effects were tested for the A-MiniDADI composite score and showed no floor effect, however a ceiling effect of 32% was found (Table 29).

Table 29 Internal consistency and floor and ceiling effects for the A-MiniDADI n = 54

A-MiniDADI	Items	Cronbach α	Mean (Range of scores)	Floor effect (%)	Ceiling effect (%)
Composite	5	0.89	78 (28 – 100)	No (2%)	Yes (32%)

Floor and ceiling effects are considered if 15% of the participants scored any of the extreme scores (20 – 100).

Test-retest reliability

For the MiniDADI test-retest reliability, the ICC value is presented in Table 30 with 95% CI.

Table 30 ICC values for test-retest reliability (MiniDADI1 and MiniDADI2 scores) *n = 30*

A-MiniDADI	ICC [95% CI]
Composite	0.67 [0.41;0.83]

Validity of the A-MiniDADI

Construct validity

The A-MiniDADI had a strong to moderate correlation with the A-DHI total, HN-Swallowing and HN-Social eating. Results are presented in Table 31

Table 31 Correlation between the MiniDADI composite score, the A-DHI total scores and the EORTC-HN35 domains n = 53

MiniDADI	Instrument/Domains	Correlation coefficient	*p* value	Correlation of full MDADI with the domains
MiniDADI composite	A-DHI total	-0.73	*P <0.001*	-0.85
	HN-Social eating	-0.73	*P <0.001*	-0.75
	HN-Mouth Opening	-0.68	*P <0.001*	-0.61
	HN-Swallowing	-0.65	*P <0.001*	-0.73
	HN-Senses	-0.59	*P <0.001*	-0.57
	HN-Dry mouth	-0.43	*P = 0.001*	-0.50
	HN-Sticky Saliva	-0.32	*P = 0.018*	-0.35
	HN-Teeth	-0.28	*P = 0.038*	-0.28

General comments

During the data collection, many of the participants expressed a high degree of acceptance of the A-MDADI. The participants also felt that the statements were reflective of their situation, either currently or at some point during their HNC journey. The participants also shared some of their dysphagia experiences, which emphasises the added value of the inclusion of PROs to facilitate conversations with healthcare professionals. In Figure 11, I quote some of the patients' statements from my field notes (here translated from Arabic).

Figure 11 Some comments from patients who participated in the A-MDADI validation study

4.5 Discussion

Swallowing can be assessed using different measures, including objective instrumental assessments (Groher and Crary, 2016). However, instrumental assessments do not capture the psychosocial impact of swallowing impairment. Understanding the impact of dysphagia on QOL is vital for HNC assessment and subsequent management. Using a consistent measure over time enables early detection of difficulties and assessment of any progression over time. Therefore, this study aimed to translate, culturally adapt and evaluate an Arabic version of the MDADI to be included in the Swallowing Outcome Package for use in the clinical setting in Kuwait. The questionnaire was validated on a broad range of patients with HNC, encompassing different HNC sites and tumour stages, treated with different modalities. In this study, cancers of the nasopharynx and larynx were the most common, accounting for 67% of the sample. The mean participant age was 50 years, and most participants were males. The sample was representative of the Arabic HNC population in Kuwait (see Chapter 2). According to the recommended guidelines for translating and testing the psychometric properties of a new instrument, the A-MDADI proved to have good internal consistency and test–retest reliability for all domains. The A-MDADI also proved to be valid in terms of construct validity when compared with the A-

DHI and the A-EORTC-HN35. This evaluation suggests that the A-MDADI can be a useful instrument when assessing swallowing-related QOL in Arabic-speaking patients with HNC. The MDADI in its original version is recommended as one of the PROs to be used in HNC in the ENT UK guidelines (ENT UK, 2021).

4.5.1 Psychometric properties

Reliability is concerned with the consistency of the instrument and is typically measured by means of internal consistency and test–retest reliability (De Vet et al., 2011). The internal consistency of the A-MDADI was determined by Cronbach α (0.93), which was comparable with that of the original English questionnaire (α = 0.96), and the other available versions that have the same statement structure, that is, two negatively phrased statements (Cronbach α = 0.84–0.95). Moreover, it is also comparable with the Brazilian (α = 0.8), Dutch (α = 0.94) and Chinese (α = 0.93) versions that have their statements unified to match the rest of the statements (adjusted the inversion in items E7 and F2). Similar results were observed in the emotional, functional and physical domains. The test–retest reliability results were also acceptable, ICC values ranging from 0.82 to 0.93, suggesting that the A-MDADI is reproducible in patients with HNC. The test-retest reliability was also comparable with that of the original version and the other translated versions (see Appendix K for a summary table of all available versions of the MDADI).

In this study, content validity was maintained by following the accepted guidelines for translation and cultural adaptation of QOL instruments, thus achieving cross-cultural validity (De Vet et al., 2011). In terms of construct validity, the A-MDADI showed strong-to-moderate negative correlation with other instruments testing similar constructs – the A-DHI and the EORTC-HN35 subscales – supporting the suggested hypotheses that the MDADI total score and subscale scores will have a negative correlation with the DHI total score and subscales, and a negative correlation with the EORTC-HN35. The composite A-MDADI score negatively correlated with the composite A-DHI score (r = - 0.85). A strong negative correlation was also observed between the emotional, functional and physical domains in both instruments (r = -0.67 to -0.76). Although the A-DHI was not designed specifically for HNC dysphagia, it is a valid and reliable instrument for quantifying dysphagia QOL. The correlation between the A-MDADI and EORTC-HN35 swallowing-related subscales varied from weak to strong (r = -0.28 to -0.75). It should be noted that the swallowing-related

section of the EORTC-HN35 is largely concerned with the physical symptoms of swallowing rather than its emotional or social aspects. The score of the social eating subscale of the EORTC-HN35 was strongly correlated with the A-MDADI composite score (r = -0.75), which was expected because many items in the MDADI are concerned with social eating, confirming that the MDADI is an instrument that captures swallowing-related QOL rather than merely a patient-reported symptom scale. Previously, the EORTC-HN35 was also used for testing the validity of the Japanese version of the MDADI; the authors reported a range of strong-to-moderate correlations with the composite MDADI score (Matsuda et al., 2018).

Moreover, when cross-validating the results of this study with a different cohort that completed the English versions of both the MDADI and EORTC-HN35, the results were comparable for HN-Swallowing, HN-Social eating and HN-Senses (all showing moderate correlations; Table 28). Criterion validity was not established in this study as there is no gold-standard instrument available for assessing dysphagia QOL. The SWAL-QOL possesses sound and strong psychometric properties (Timmerman et al., 2014) and has been considered as a gold standard in some studies validating a new version of the MDADI to determine criterion validity (Speyer et al., 2011 and Yee et al., 2020). Using the SWAL-QOL in the present study would have been useful to enable further comparisons with the existing body of literature; however, there is currently no validated Arabic version of the SWAL-QOL. In the original version of the MDADI, the Performance Status Scale for head and neck cancer (PSS-HN) in its three subsections was considered as a gold standard for criterion validity; however, only the global, emotional, physical and functional domains were tested for validity and not the composite score. The PSS-HN is a clinician-rated tool and not a PRO measure, therefore it was not used for validating the A-MDADI in the current study, as I only used similar PROs.

In the present study, no floor effect was found in any of the A-MDADI domains; however, a ceiling effect was observed for both the global (39%) and the functional (20%) A-MDADI domains, Table 24). A ceiling effect may affect the responsiveness of the scale since patients who have high scores at baseline cannot show further improvement (De Vet, 2011). The results of this study indicate that the A-MDADI cannot detect improvements in the functional and single item global domains and therefore cannot be used as a summary

score to compare outcomes. Hutcheson et al. (2015) suggest the use of the composite MDADI score when comparing outcomes.

In the original version of the MDADI, Cronbach α = 0.96 (Chen et al., 2001), which was high and suggest item redundancy, this was confirmed later, and it was suggested that the MDADI could be shortened to 5-items (Lin et al., 2021). The internal consistency of the MiniDADI α = 0.9, suggesting an acceptable value. Regarding the Arabic shortened version of MDADI (A-MiniDADI), the results demonstrated that the internal consistency was satisfactory (α = 0.89) and comparable with the English MiniDADI (E-MiniDADI), whereas the test reproducibility was acceptable (ICC = 0.67). The retrospective nature of our previous preliminary work (Lin et al., 2021) did not allow the testing of the reproducibility of the E-MiniDADI. Also, it should be noted that the composite A-MiniDADI score had a ceiling effect of 32% (Table 29). In the long version of the A-MDADI, no ceiling effect was found for the composite domain, however, the functional domain had ceiling effect (20%), therefore, this could be partially explained by the fact that two items of the MiniDADI are from the functional domain. It is therefore important to further investigate the MiniDADI prospectively from an impaired baseline to establish its responsiveness. A suggested time point is three months post (C)RT and onwards as evidence suggests that this time point shows the most severe patient-reported dysphagia (Wilson et al., 2011; Roe et al., 2014). Concerning validity, E-MiniDADI was valid in terms of known-group validity (construct), similarly, the A-MiniDADI showed strong-to-weak correlation with the A-DHI and EORTC-HN35 swallowing-related domains, suggesting that the MiniDADI is a valid tool. As suggested in the original manuscript (Lin et al., 2021), the MiniDADI should not yet be used in research or clinical practice as it warrants further testing.

4.5.2 Responses and statements

The problem with the inversion in the two statements (E7 and F2) was apparent in the pre-testing stage as some of the participants did not notice the negation; however, no active measures were taken to reword the statements. It is worth mentioning that if these two statements are unnoticed, it could lead to a false expectation of an MCID, without it actually being an MCID (the between-group MCID for the MDADI is reported as 10-point difference). The fact that no active measures were taken may seem counter-intuitive as a 'new' measure should not be created without correcting the issues of the previous version;

however, rewording the statements may have limited cross-cultural comparisons with the original MDADI and other translated versions. Similar scoring issues were identified in the Danish and Swedish versions of the MDADI (Carlsson et al., 2011; Hajdu et al., 2017). In both versions, when inconsistencies in scoring were identified, scores were reversed in an appropriate manner (score reversal). No such issues were reported in the original (English), Korean and Italian versions of the MDADI (Chen et al., 2001; Kwon et al., 2013; Schindler et al., 2008). In the Dutch, Brazilian and Chinese versions of the MDADI, all items are affirmative. A potential solution for the time being is to highlight the two inverted items to draw the patients' attention until the further testing of the MiniDADI is complete.

The use of 'no opinion' in the response scale was an issue highlighted in the present study and in the Swedish translated MDADI (Carlsson et al. 2011). Carlsson and colleagues (2011) suggest that the interpretation of this response may be ambiguous, with uncertainty about whether the patient did not understand the question, or they did not perceive the underlying concept to be a problem or it was just not applicable. When faced with irrelevant statements such as 'My swallowing difficulty has caused me to lose income' for an unemployed person, it may be difficult to decide between 'no opinion' or 'strongly disagree' (Yee et al., 2020). This may reduce a patient's score spuriously. In the Arabic version, this response was changed to 'I don't know', and although it was chosen for several statements, it was mostly used for item F1: 'others find it difficult to cook for me'. This change in phrasing may enhance the choice of this response.

4.6 Limitations

A major limitation of this study is the possibility of coverage bias; there was only one participant who is tube-dependent, and therefore, the questionnaire lacks input from patients who are tube dependent, and the results of the study may not be generalised to those patients. Moreover, the sample size is relatively small and did not allow for between-group comparisons to establish known-group validity (e.g., comparison between age groups). In addition, due to the cross-sectional nature of the data, responsiveness to change of the A-MDADI was not determined and therefore it may require further testing, however since the psychometric properties are comparable with the original version, it is expected that the translated version will also be sensitive. For the test-retest reliability, it is recommended to have at least 50 patients (De Vet et al., 2011), this however was not

met in the current study. The implication of this limitation is that ICC values could have been less if the sample size were larger.

4.7 Clinical implications

The A-MDADI can now be used and implemented in routine clinical practice to capture patients' perspectives on the impact of swallowing on everyday living. Capturing patients' perspectives is important; however, it is evident from the literature that PRO measures and objective assessments are poorly correlated, and therefore PRO measures should be complimentary to objective outcome measures and should not displace them. Introducing the MDADI as a PRO in clinical practice could facilitate discussions with healthcare professionals and allow them to monitor patients who are at risk of dysphagia. Both versions of the MDADI, the original and the Arabic version, will be included in the Swallowing Outcome Package to include the diverse patients with HNC in Kuwait. The MDADI should be administered at baseline to facilitate comparisons over time, to understand patients' perspectives on the impact of treatment and to obtain an indication if patients' situation should change and may require further investigation. The MDADI can be administered to patients (either electronically, if feasible, or on paper) while they are waiting in the waiting room for their appointment, or online through a tele-health session. The outcomes of the questionnaire may become a conversation between speech and language therapists and patients, and interventions can thus become more patient centred. The A-MDADI can also be used in any setting where patients speak or prefer the use of Arabic. Many Arab patients travel or live abroad, and they may seek treatment in facilities in the UK, USA, or other European countries; thus, the A-MDADI could be valuable especially if these facilities already collect MDADI data.

4.8 Implications for future research

Future research is warranted to understand the swallowing-related QOL in HNC patients in Kuwait. Studies should also include patients who are tube dependent to uncover their experiences. Longitudinal studies are required to assess the reproducibility and responsiveness of the 5-item A-MiniDADI in a large group of patients with HNC. Moreover, it is important to consider how to include illiterate patients in patient-reported swallow outcomes, as some may require proxies to fill-out the questionnaires, which may impose bias. The MDADI is widely reported in HNC literature, however, since there were no Arabic

versions none of the studies reported on the MDADI within the Arabic-speaking populations. Future research may consider using the MDADI as an outcome measure within different clinical settings (i.e., settings in neighbouring and Arabic-speaking countries) and to compare outcomes, to understand the swallowing-related QOL profile in patients with HNC.

It has been suggested the 'between group' MCID is 10-point based on different clinical anchors (comparison between patients) (Hutcheson et al., 2015). With regards to longitudinal changes, it has been suggested that 20-points constitutes the MCID (within group comparison; Lu et al., 2012). However, the suggested within-group MCID was not empirically tested and was not provided with rationale. Further investigations are warranted as identifying the MCID would be a useful metric for meaningful comparisons. In Chapter 6, I will thoroughly discuss the concepts of MCID.

Chapter 5: Swallowing Outcomes Package: Measures of Dietary restrictions

In this chapter, I shall evaluate clinicians' perceptions and acceptance of two scales that address dietary restrictions, the Functional Oral Intake Scale (FOIS) and the Performance Status Scale – Normalcy of Diet (PSS-NoD). The results of this chapter will inform which, if either, of the two scales should be included as part of the Swallowing Outcomes Package.

5.1 Background

The ability to safely swallow food and drink items may be jeopardised in patients with head and neck cancer (HNC), and therefore patients may have to restrict their diet during treatment and sometimes throughout survivorship. These restrictions may be self-imposed owing to difficulties in managing some food and drink items or recommended as an intervention by speech and language therapists (SLTs) to compensate for the swallowing impairment, or to maintain safe or more comfortable swallowing (Cichero et al., 2016; Crary, Carnaby Mann and Groher, 2005). The functional impact of swallowing impairment on diet is commonly done during clinical swallowing evaluation (CSE) or instrumental assessment (Crary et al., 2005). The importance of documenting dietary limitations is to inform therapeutic interventions, monitor eating and drinking abilities and to measure changes over time. Failure to compensate for eating and drinking limitations risks malnutrition, dehydration and reduced quality of life (QOL; Beck et al., 2018; Swan et al., 2015).

5.2 Methods of assessing dietary restrictions

Dietary restrictions are usually assessed using clinician-rated ordinal scales. The two most commonly used scales are the Performance Status Scale for HNC (PSS-HN; List, Ritter-Sterr and Lansky, 1990) and the Functional Oral Intake Scale (FOIS), which was originally developed for stroke patients (Crary et al., 2005). Other scales include the Functional Intraoral Glasgow Scale (FIGS; Goldie et al., 2006) and the International Dysphagia Diet Standardization Initiative Functional Diet Scale (Steele, et al., 2018).

The PSS-HN is a validated tool specifically designed for patients with HNC. It has three subsections, each assessing a different concept: the understandability of speech, eating in public and the normalcy of diet (List et al., 1990). The understandability of speech measures the degree of which the clinician is able to understand the patient's speech and it has five items, scored from 0 – 100 (higher scores indicate better speech understandability). The eating in public subscale also consists of five items and is based on patient-report on how comfortable he or she feels about eating and drinking in the presence of others (scores range from 0 [eats alone] and 100 [no restrictions of food, place or company]). Whereas the normalcy of diet subscale (PSS-NoD) is a 10-item scale that is concerned with the patient's ability to eat specific textures arranged in order of difficulty. The PSS-HN was developed in consensus between speech and swallowing experts; however, the process by which the categories descriptions and scores were derived remains unclear. Each subsection can be reported independently as each provides unique information on different functional impairment. The PSS-NoD subscale is the most reliable out of the three subsections (Khan et al., 2015). For the purpose of this study, I will only focus on the PSS-NoD subscale. Figure 12 shows the PSS-NoD scale.

Figure 12 The Performance Status Scale – Normalcy of diet subsection

Performance status scale - NORMALCY OF DIET

100	Full diet (no restrictions)
90	Full diet (liquid assist)
80	All meat
70	Raw carrots, celery
60	Dry bread and crackers
50	Soft chewable foods (e.g., macaroni, canned/soft fruits, cooked vegetables, fish, hamburger, small pieces of meat)
40	Soft foods requiring no chewing (e.g., mashed potatoes, apple sauce, pudding)
30	Pureed foods (in blender)
20	Warm liquids
10	Cold liquids
0	Non-oral feeding (tube fed)

The texture categories of the PSS-NoD are based on the American diet. In 1996, the original description of level 90 of the PSS-NoD was changed from 'peanuts' to 'full diet with liquid assistance' (List et al., 1996) with no rationale being offered for this substantial alteration. Some studies continue to report on the original description of the category 'peanuts' rather

than the new substitution (Eldridge et al. 2019; Zuydam et al., 2020; Van Abel et al., 2019). This may affect comparisons between studies as the descriptions may not be equivalent in their level of difficulty.

The scale is easily scored by any healthcare professional following a brief patient interview, and requires no formal training (List et al., 1990). The PSS-NoD has scores ranging from 0 to 100 (higher scores indicate superior performance). If the patient is tube dependent but also consuming food orally or can tolerate solids but not liquids, then the scoring should be based on solid food (the most difficult consistency; Health services and research outcomes, 2010).

The inter-rater reliability of the PSS-NOD scale was high for both trained and untrained staff (Kappa = 0.88 and 0.84, respectively). The scale was validated using known-group validity testing (comparing PSS-HN outcomes between HNC and breast cancer patients), content validity (comparing differences in PSS-HN outcomes between different treatment groups of patients with HNC) and construct validity (compared with the Karnofsky functional status scale; List et al., 1990). A cut-off point for good performance was suggested as > 50; however, no clear rationale was provided for this conclusion (List et al., 1997). Despite these limitations, the PSS-NoD remains the most reported diet scale in head and neck cancer research and in clinical practice, and is sensitive to capturing changes from baseline to twelve months post-treatment (Patterson et al., 2014). It was included as an outcome measures in the United Kingdom audit - Dataset for Head and Neck Oncology (DAHNO; 2009).

The Functional Oral Intake Scale (FOIS; Crary et al., 2005) is an alternative scale for the assessment of food restrictions. It was initially developed for use with stroke patients. However, the FOIS is beginning to gain popularity in HNC population and has been utilised as an outcome measure in several studies (e.g., Kamal et al., 2019; Kotz et al., 2012; Moroney et al., 2020; Starmer et al., 2017; Van Abel et al., 2019). The scale was initially developed by examining swallowing-related literature to identify the type and amount of food and drinks a patient may consume with or without limitations, resulting in a scale of 10-items. The initial 10 items were then reduced to seven items after a pilot period. The FOIS is an ordinal scale, with two levels: the first level has scores from one to three and is used to grade tube dependent patients, whereas level two includes scores from four to

seven and describes oral feeding. Score one is indicative of a complete tube dependency, and level seven representing consumption of a normal diet. To score the scale, clinicians may rely on information that is easily accessed from varied sources, including: medical charts, dietary journals, patient report, and/or caregivers (Crary et al., 2005). Figure 13 shows the FOIS.

Figure 13 The Functional Oral Intake Scale (FOIS)

Functional Oral Intake Scale (FOIS)

Level	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

The FOIS proved to be reliable and valid in stroke patients, with the interrater reliability (k) ranging from 0.86 to 0.91. The FOIS was also valid in terms of criterion validity when compared with other related tools and proved to be sensitive in both stroke and HNC patients (Crary et al., 2005; Im et al., 2020). This scale is quick, but relies solely on a recording of feeding method and the description of undefined consistencies, thus providing no detailed information on diet textures.

Another scale that aims to assess functional outcomes, including eating and drinking abilities, is the FIGS (Goldie et al., 2006). The FIGS scale assesses the patients' functional status in terms of speech, swallowing and chewing. Neither its origin nor its psychometric properties have been reported. In 2018, Steele and colleagues created a Functional Diet Scale that aims to capture the dietary restrictions as recommended for the patients based on the International Dysphagia Diet Standardization Initiative (IDDSI) framework. This scale is intended to be used for those with oropharyngeal dysphagia from infancy to older people, and has demonstrated strong reliability and validity (Steele et al., 2018). The IDDSI

framework has yet to be implemented in Kuwait, and so its functional diet scale was not a candidate for inclusion in the Swallowing Outcomes Package.

This chapter will focus on the PSS-NoD and FOIS. These scales are a valuable additions to the CSE; however, they are not intended to be used in isolation in the assessment of swallowing impairments as they do not provide information on the pathophysiology or the biomechanics of swallowing.

5.3 Rationale and aim

The addition of a diet scale into the Swallowing Outcomes Package will be useful to systematically document diet restrictions and allow comparisons over time. Studies have shown that both the FOIS and the PSS-NoD can be used by healthcare professionals to record restrictions. However, it is important to understand how clinicians in Kuwait identify these restrictions and record them on the dietary restriction scales, especially given that the PSS-NoD was created based on an American diet, which may not reflect the diet diversity in other cultures, countries and regions, including Kuwait. Moreover, as these are clinician-rated scales, it is also important to understand the views of and acceptability of the scales by the clinicians to include either one or both scales in the Swallowing Outcomes Package.

This study aims to explore clinicians' understanding of and views regarding the FOIS and the PSS – NOD.

Objectives:

- Explore the process in which clinicians reach decisions for scoring dietary restrictions on the PSS-NoD and FOIS.
- Identify clinicians' opinions and acceptance of the two diet scales.

5.3 Materials and methods

5.3.1 Ethical considerations

This study was considered as a low risk study, and was granted immediate approval by Newcastle University Ethics Committee. It was also granted ethical approval from the Research Committee at the Ministry of Health – Kuwait.

5.3.1 Study design

This study utilised a qualitative design of cognitive interviewing to explore and identify the clinicians' opinions and decision making when using the PSS-NoD and FOIS scales. Although focus groups are excellent in generating discussions and offer unique observations, this format of data collection was not selected here. Focus groups rely on interactions between the participants, which is facilitated if the participants know each other or have a common background (Green, 2007). However, factors such as years of experience and employment hierarchy may compromise the flow of discussion within the group (Curry, Nembhard and Bradley, 2009). It is also suggested that focus groups are not suited for assessing existing instruments because they explore 'topics' rather than evaluating specific questions or items in a tool. Furthermore, focus groups are not suited for 'think aloud' (Wiillis, 2005). Therefore, one to one interviews were chosen as a data collection method to allow clinicians to practice 'think aloud' freely with less self-consciousness and enable further follow-up discussion without regard to the opinion of peers or seniors in the group. They also offer pragmatic timetabling advantages.

Cognitive interviewing is the collection of verbal information to explore the methods respondents (interviewees) use to understand, process and respond to the materials under investigation (in this instance, a comparison of rating scales). This information assists appraisal of the material being tested (Beatty and Willis, 2007; Willis, 2005). Using the conventional interview design, in which clinicians' respond to a series of semi-structured or structured questions, may not identify all the possible problems that clinicians could encounter during the scoring process. Most clinicians in Kuwait have no prior implementation experience of either one or both scales in clinical practice, which may inevitably limit their insight concerning potential difficulties. Cognitive interviewing using case vignettes was considered an appropriate method to evaluate and identify any hidden difficulties or misinterpretations clinicians may encounter during scoring the two diet

scales, especially when rating food items that are not customary among the originating population. Using this method paves the way for a better understanding of clinicians' comprehension, retrieval of information, reaching to decisions and scoring the scales.

5.3.3 Participants

Speech and language therapists (SLTs) and dieticians (D) who work or have experience with working with HNC were invited to take part in this study. All clinicians were working in Kuwait, and they were identified and approached through formal and informal professional networks and not via a gatekeeper (e.g., a manager or a clinical supervisor). This minimised any coercion to participate. The clinicians were approached by myself and asked if they were interested in taking part in the study interview. Those who expressed interest were given a further explanation of the study, a participant information sheet and were asked, if they were content to proceed, to choose a time and a location of their convenience for the interview.

5.3.4 Data collection

I employed two cognitive interviewing techniques, the 'think aloud' and the retrospective probing technique.

5.3.5 Case vignettes and booklet

Case vignettes (short hypothetical descriptions, (Willis, 2005), provided the participating clinicians with different scenarios of HNC patients with different abilities of oral or non-oral intake. Case vignettes offer a simulated real world situation allowing respondents to envisage the scales in action. When used in conjunction with cognitive methods, such hypothetical scenarios expose the steps of the response process according to varying circumstances and identify potential problematic areas of the tool under investigation (Morrison, Stettler and Anderson, 2004).

I created the vignettes based on common swallowing and dietary issues faced by HNC patients prior to, during or post-treatment. Each vignette represented a unique case, and a variety of diet textures were included. A total of 11 cases vignettes were created. The vignettes were shared and discussed with the supervisory team, and were then rehearsed with a fellow PhD/SLT student to iron out any issues that needs to be addressed. Examples of the vignettes can be found in Appendix L.

The case vignettes were presented in a booklet, incorporating full description of the FOIS and PSS-NoD rating instructions. An initial sample vignette was used as an example to demonstrate the 'thinking aloud' technique and for the participants to recognise that each case should be scored on both scales. Each vignette was supplemented with a three-day diet journal, or a description of consumed food items. I placed the two diet scales (FOIS and PSS), on the opposite page of each case, allowing the clinicians to have the information and the scales within their sight without having to flip between pages. The booklet also included a food glossary describing uncommon or ethnic food items, and a photo gallery for visual reference (See Appendix L for examples of food glossary and gallery). The participants were given the vignettes during the interview.

5.3.6 Interviews

Participants were asked to use the 'think-aloud' technique while scoring the vignettes. As the behaviour of 'thinking aloud' is unnatural, it requires some practice. Therefore, prior to the interview commencement, I invited each participant to try and visualise their home and think about how many windows there are in total and asked them to verbalise what they were seeing and thinking while counting (Willis, 2005). I also included an initial vignette as a practice, to ensure that they had fully grasped the task. After the vignettes were score while 'thinking aloud', I conducted a retrospective probing interview. The participants were informed that they can 'think aloud' in their preferred language in either English or Arabic, without being concerned of having to think in a specific way.

Thinking aloud reduces or eliminates the interviewer-imposed bias, as the interviewer has minimal or no contribution to the process. This was especially important as I was interviewing my colleagues and peers. Secondly, the technique required minimal interviewer training and its open format allowed for the emergence of unanticipated information. In contrast, the follow-up probing technique allows more focused investigations (Willis, 2005).

The interviews were conducted during or after working hours at the clinicians' break/free time. The booklet was created in English to maximise participation since both scales are in English and the common spoken language in workplace is English. The interviews were audio-recorded.

As English is a common method of communication in hospital and clinical settings, and as the vignettes and the scales were both English there was a lot of code-switching (between English and Arabic languages) during interviews. Whichever language the clinicians used; I would interact with them using the same language. The interviews began with a thanks for their participation, followed by going through the participant information sheet. All clinicians were reminded that everything recorded, and anything said during the interviews would remain confidential. They all signed a consent form (Appendix M). Rapport was already established as I have worked or have been in a professional contact with most of the clinicians previously. In some cases, some clinicians articulated feeling uncomfortable about the process: 'I feel like I am being examined' or 'Can you tell me later how I did?'. I would acknowledge their nervousness and remind them that this was not a test of their skills, rather a way for me to understand the scales and their utility in clinical practice. This would generally make them feel more at ease. One of the clinicians was quiet the whole time and then declined to be recorded despite signing a consent form.

5.3.7 Analysis

The interviews were transcribed verbatim, in the same language as the interview. Arabic language words/expressions were translated to English when transcribing the interviews. The translation of Arabic words was conducted carefully to preserve the original meaning as much as possible.

The interviews were analysed following Tourangeau's question response model (comprehension, retrieval, judgement, and response formulation; Tourangeau, 1984). *Comprehension* encompasses to what degree participants understood the instructions, questions, and linking concepts. *Retrieval* refers to the ability to recall the information required to answer/score the questions, and *Judgement* is concerned with making a decision based on the recalled information. Finally, *Response* refers to mapping the generated answer to the response option. Any identified codes that lay outside of this model, were organised under themes as described by Willis and Artino (2013). This was achieved by combining similar codes related to each item in the interviews under common themes (Eland et al., 2020; Willis and Artino, 2013). The retrospective interviews were also coded and organised by another researcher (JL), and all results were then discussed and reviewed with her.

Initially, the model was used to analyse the 'think aloud' process for 10 vignettes separately, and the follow-up interview. The results were then aggregated and organised under the associated themes. Any findings/quotes which emerged from the 'think aloud' process are identified as such below. All other findings were derived from the follow-up interview.

5.4 Findings

5.4.1 Participants and demographics

In total, 16 clinicians were invited to take part in this study, eight SLTs and eight dieticians. All the SLTs and seven of the dieticians were approached by myself. One of the dieticians was identified through snowballing sampling (*i.e.,* through a referral made by one of the participants; Biernacki and Waldorf, 1981).

A total of 10 clinicians participated in this study, six SLTs and four dieticians. Reasons for not taking part were either being busy or not having substantial experience with HNC dysphagia. One clinician did not reply. The interview duration ranged between 45 and 90 minutes. Nine of the 10 participants had six years or more of total working experience, and seven clinicians had working experience with HNC of between three and five years, see Table 32. The clinicians are identified as either SLT-letter or D-letter – they were not given names as the majority were females. As there was a limited number of clinicians, in order to protect their anonymity I refrained from giving them aliases as it would then be easy to identify them.

Table 32 Experience of clinicians who participated in the dietary restrictions interviews

Profession-participant	Years of experience	Dysphagia experience	HNC experience
SLT-L	6 years or more	6 years or more	3–5 years
SLT-D	6 years or more	6 years or more	3–5 years
SLT-T	6 years or more	3–5 years	1 month
SLT-Sh	6 years or more	3–5 years	1–2 years
SLT-F	6 years or more	6 years or more	3–5 years
SLT-Y	3 – 5 years	3–5 years	3–5 years
D-M	6 years or more	3–5 years	3–5 years
D-S	6 years or more	3–5 years	3–5 years
D-R	6 years or more	3–5 years	3–5 years
D-N	6 years or more	3–5 years	1–2 years

5.4.2 Themes

The four stages of cognitive response process (comprehension, retrieval, judgement and response) will be reported as themes. Another theme has emerged and it will be reported as the theme 'opinions of scales'.

Theme one: Comprehension

The first theme concerned clinicians' understanding of the scales' instructions and categories, and it is organised under two sub-themes:

- **Instructions**

Most clinicians found the instructions to be clear, and most of them were certain of how they were supposed to score the scales. When asked for their views of the instructions, one of the clinicians said:

SLT-F: [The instructions] were very clear, in one of the cases I needed to go back to the instructions. Excellent.

However, some issues were noted during the 'think aloud' process; it was evident that some of the clinicians wrongly scored patients on their clinical recommendations, rather than on the patient's current consumption. For example:

D-N: For functional oral intake, total intake of a single consistency. Number four. This is what we're going to do with him. Thick puree. For the performance status scale, we can try full diet, no not full diet, we start from where … warm liquids ... puree food. We can start with puree food as a trial.

Another dietician made the same mistake but self-corrected when she reread the instructions and realised that she was not following them appropriately. Later on in the follow-up interview she said:

D-R: At first I was doing it wrong, I thought that I had to recommend nutritional supplements and recommend what texture was best for the patient, but I realised that it was wrong in the third case because I read the instructions again so I fixed it.

An SLT asked twice during the 'think aloud' process, and then in the follow-up interview she said:

SLT-T: There are some things that are confusing, so for example on the performance status scale we had one of the patients that was dependent on tube, but also had minimal oral intake … So it was clear on the functional oral scale, but here [PSS] it was non-oral feeding and then nothing in between. So what if he was tube fed but also had minimal intake?

The PSS-NoD instructions specify that patients who are using a feeding tube but are also consuming food orally should be scored based on 'solid foods'.

The outcomes of the 'think aloud' protocol and the probing interview demonstrated that some of the clinicians had issues with the comprehensibility of the instructions. This, presumably, could either be because they did not read the instructions thoroughly or because the instructions were not clear enough. However, most found no difficulty, in line with the published evidence suggesting that neither scale requires special training, beside the basic description of the instructions (Crary et al., 2005; List et al., 1990).

- **Categories**

Some comprehension issues emerged regarding the scales' categories, mostly in the PSS-NoD categorisation, for example, during the 'think aloud' process, one clinician was clearly confused:

> *SLT-Y: The other one is ermmmm all meat? Why all meat! I don't understand!*

The 'all meat' description caused confusion for many of the clinicians (7/10). In the follow-up interview it appeared that the clinicians were contemplating why this category was there, and how to use it in scoring. Clinicians were uncertain of what this category represented:

> *D-M: Raw carrots and celery. Ok. All meat. Ok. What's the difference between 'all meat' and 'raw carrots and celery'? Maybe the patient can eat meat, the chicken the fish and can eat carrots. I don't know, I don't know. I feel like with practice it would be easier.*

Similar confusion issues were faced by other clinicians:

> *SLT-T: … it's raw carrots and celery, all meat! Ok so some meat is chewable, some meat is really hard, some requires … I thought the FOIS was more direct and to the point whereas this [PSS] was a bit confusing.*

And also:

> *SLT-T: 80, 70, 60 don't make sense to me, I understand that dry bread and crackers they crumble, but … and these require more chewing. But this [70] and this [80] I don't see a difference. A little bit. I feel like they blend together. They need to be more specific. So 0 to 50 and 90 to 100 make sense. But 60, 70, 80 don't make sense. I don't understand them 100%.*

A clinician was wondering about the use of this category for scoring vegan/vegetarian patients:

> *SLT-F: … The vegetarian one. Because it says 'all meat', but he's not gonna eat meat … So yeah which one 'all meat'? He doesn't eat meat, so the upper level?*

It was notable that the majority of the clinicians found some categories, especially the 'all meat' category, to be confusing. This category did not seem logical to many clinicians. This confusion cannot be linked to differences in, for example, the role of meat in the Kuwaiti culture or the surrounding regions. The role of all types of meat in the Middle Eastern and surrounding regions cuisine is unquestionable; while acknowledging the fact that it reserves a certain cultural individuality in the preparation methods, meat retains its common known characteristics.

As the majority of clinicians who participated in this study found some PSS-NOD categories to be confusing, I investigated the distribution of the PSS-NoD scores at different time points (baseline and post-treatment) to understand if all scores were useful and were being utilised. This was explored by performing a secondary data analysis on an existing dataset of patients treated with (Chemo)radiotherapy (C)RT). I also looked into the literature for available data for the purpose of comparison between results. This will be introduced later in the chapter.

Theme two: Retrieval

Information recall or retrieval can be derived from memory, or the available information at hand. The clinicians employed or needed several strategies in order to recall the required information. This happened either by recalling the consistency of food items from memory, describing the textures, or by referring to the food glossary and gallery. Also, the information from the diet journal was helpful.

Some examples from the 'think aloud' process:

> *SLT-Y: ermmm ermmmm not full diet of course. Let's say ... warm liquids, pureed food in blender? Yeah, pureed food in blender because there's mashed potatoes, custard, and yogurt with honey.*
>
> *D-R: Jelly, jelly … this is liquid.*

- **Information sources**

In a real clinical situation, the clinicians described several sources that may help with retrieving information in order to reach a decision. Most clinicians agreed that the patients and their caregivers are the key information sources, with some clinicians choosing to be more thorough and depend on other observations. This was demonstrated by them saying:

SLT-L: The patients, maybe the caregiver as well.

SLT-T: I think the best way honestly is to go during mealtime and see what the patient is eating. And asking the family members.

D-M: The file ... Well not only the file, the patient or their relative. Even the tray observation, we can see what the patients ate and didn't.

Theme three: Judgement

This theme covers the ability of the respondents to assimilate the information retrieved and reach a decision based on the available data. From the 'think aloud' process, it was evident that the clinicians could or could not reach a judgement based on the specific information at hand, for example:

SLT-T: Ok. So he's on a … I would say fork mashable maybe? Fork mashable. So he would ... on the functional oral scale he would be in levels 4 to 7.

SLT-T: I can't tell without seeing the patient!

D-R: Ok so he's tube dependent. Ermmm levels 1 to 3. Ermmm

In the follow-up interview, the clinicians reported using several methods to reach their decisions using the vignettes:

SLT-T: Because of the variation I feel like I got the information I needed [The variation of food items in the diet journal].

SLT-L: Based on the food provided [in the diet journal], sometimes it's not very obvious but you can tell based on how the food is prepped, for example chopped salad.

D-M: There are specific food items that delete all the others. For example, Irani bread is very difficult, so if the patient can have Irani bread then they can have everything.

D-R: First the diet journal, and the symptoms the patients are suffering from.

- **Limitations of the vignettes:**

There was some missing information from the vignettes that the clinicians thought limited their ability to appropriately rate the scales – for example, the quantity of fluid intake, and the consistency of certain food items. This was illustrated by them saying:

SLT-F: So, for example, a patient complains of dehydration but in the diet you don't see extra intake of water.

SLT-F: … So the quantity would be really useful to have.

SLT-F: There are some cases you don't know what to choose, but you make your decision based on the information you have.

SLT-L: … There was one who had issues with liquids, but the liquids were not mentioned in the diet journal.

SLT-D: Some things were very obvious, others were not, for example, where I wasn't sure of the soup type or consistency. Thin or puree. Even vegetable soup can mean something.

SLT-D: Swallowing time, pattern. Most said difficulty swallowing [information provided in the vignettes], but the stage was not specified, the delay. If one side was more painful than the other.

Similarly, the dieticians were also keen to have insights into the volume of fluid intake, and other oral symptoms:

D-M: For example, dehydration, how much fluid they're having?

D-N: … Ermmm, for example, coughing while eating, the food is coming out. Drooling. I would be able to make better decision [missing information].
D-R: The amount of water the patient is having, and the temperature ... you know for the PSS.

Theme four: Response

Response refers to mapping the judgement onto the appropriate response category. During the 'think aloud' interview, it was unclear how the clinicians arrived to their responses as most of the time the clinicians remained quiet when choosing their response, or they would just say phrases like 'Ok. This'. Or 'I think it's this one'.

SLT-Y: So ermmm but there's mashed potatoes, so maybe soft food requiring no chewing? So 40.

In the follow-up interviews:

> *SLT-Y: So for example the patient is aspirating but still eating. So when I score it, it becomes confusing.*

Moreover, also in the follow-up interviews:

> *SLT-D: The second one [PSS], because they already gave me examples. [Easier to score]*
>
> *SLT-T: ermmm so it was basically looking at the consistency and texture of the foods they were eating, and then scoring that in my brain as in this is mashed or this is fork mashable or this is blended and then looking at the scale and seeing ok he is doing this but more of this or more of that. Does it make sense?*
>
> *SLT-L: For example, I chose puree food, but it did not specify the liquids? Maybe the patient has issues with liquids. So I just assumed that if he can manage puree then he can manage liquids. But maybe he can't.*
> *SLT-F: With regard to FOIS it's easier because it's two levels, tube dependent, if the patient is not tube dependent then you can only have four levels … the PSS is based on the diet. The more information I get on the diet, the more I can use the PSS.*
>
> *D-M: the first one [FOIS] because it's categorised into two, total oral intake and tube fed. So if the patient is on oral intake we'll end up with four choices. Easier.*

Another issue with the categorisation was suggested by a dietician:

> *D-R: for the liquids, it's only thin liquid, why not all three levels? Even for the puree! They describe two types of soft food. But that's not the case for the liquids and puree!*

Moreover, additional food examples were thought to be beneficial:

> *SLT-F: The normalcy of diet, I felt like we can have more categories, or more examples can do! For example, dry bread and crackers, ok what's similar to dry bread? Soft chewable food has lots of examples, but here [dry bread] you don't have as much. So you need to do more thinking in order to decide. Just more examples.*

Theme five: Opinions of scales

This theme was generated from common codes identified in the analysis process and it describes clinicians' opinions on each scale and their component levels. The theme has three sub-themes: acceptability/preferences, clinical practice and communication with others.

- **Acceptability/preference:**

All clinicians thought that the scales were acceptable, with some expressing a preference for one over the other, and others saying that both scales were useful and complemented each other.

Regarding FOIS, one clinician said:

> *SLT-Y: I prefer the first one [FOIS], I feel like its more obvious. The second one [PSS] is a bit confusing. And it depends on the food, preparation, the way the food is cooked at home….. To me it feels more accurate [FOIS].*

Another clinician stated:

> *SLT-T: To me I thought the functional oral intake [FOIS] was more direct and to the point. The other one was more detailed. So think as an SLT if someone tells me for example total oral intake with no special preparation I would understand what's happening. I wouldn't need all the details under this one [pointing at the PSS].*

Both quotes indicate that clinicians agree that the PSS requires more details in order to score, which is supported by a statement made by another clinician:

> *SLT-F: FOIS is much easier. Maybe because I use it a lot … you can easily use it with the provided information. You don't need a lot of patients' information to score. Basic information and you get a level!*

On the contrary, and for the same reason given for not preferring the FOIS, a clinician stated:

> *D-N: …This one [FOIS] I feel it wasn't very specific. I didn't like it!*

The PSS was described by one of the clinicians as:

> *SLT-D: I felt like the second scale is more descriptive and detailed [PSS].*

And another clinician said:

> *D-M: The second one is very useful [PSS] …. So this one [PSS] is very individualised. It's better.*

Agreed by another clinician:

> *D-N: If I'm comparing the two scales, I feel like this one is better [PSS]. It has more details.*

- **Clinical practice**

Clinicians were divided as to which of the scales would be more suitable for clinical practice, with some believing that using both scales would be beneficial. One of the clinicians said:

> *SLT-T: So if I were to use a scale I would use the functional oral intake. I think.*

And then later, when I asked her which of the scales she would use in her clinical practice, she said:

> *SLT-T: FOIS, but if I am working with HNC maybe I would use the PSS.*

In other instances, the PSS was preferred as it provides specific details:

> *D-M: The first one is very general [FOIS]. I mean it's not very specific. But if I want to be more elaborative, which I usually am, I'd ask the patient what foods they're more comfortable with. For example, hummus, mixed stuff, the patient would tell me. So this is more specific [PSS], to avoid errors and adding things the patient cannot handle.*

On the other hand, some clinicians thought that using both scales would be ideal as one complements the other. For example, this is how one of the clinicians described both scales:

> *D-R: The first one does not explain everything, so the second one can give us the details we need. We should consider the scales as a brother and a sister.*

Similarly, another clinician voiced the same thought:

> *SLT-F: I felt like they [FOIS and PSS] complement each other. I'm used to using the FOIS, so when I see a patient, for example let's say he's tube dependent but with consistent oral intake. Ok, what's the consistent oral intake? I'll check the other scale.*

Interestingly, all but two clinicians thought that adding the scales as an outcome measure in routine clinical practice would be beneficial. This was illustrated by their responses once I asked them how useful they thought the scales were, and if not having them would affect their practice:

> *SLT-F: No it wouldn't, but it's good to have something to display your findings in a way that's used worldwide.*
>
> *SLT-L: No.*

The views were divided over which of the scales would be more sensitive to capturing changes over time, with the majority believing that the PSS would be more sensitive. Reasons for disagreement included tube dependency and category descriptions. One clinician said:

> *SLT-Y: ermmm when it comes to this the second one [PSS] is better ... because it's more specific regarding consistencies. The first one [FOIS] is more general. You know? The second one [PSS] can tell you if the patient has warm or cold liquids, and the solids ... how are the solids? Chewable or raw ... you know?*

Similar thoughts were expressed by other clinicians, agreeing that the PSS provides more details, therefore allowing more accurate comparisons. Another example is:

> *SLT-D: This one [PSS] is more detailed and has variety. With this one [FOIS] I feel like there is a gap between scores. We want details!*

In contrast, other clinicians believed that it depended on the patient's oral status at the time of diagnosis i.e., whether they were tube dependent or oral feeding.

> *SLT-F: ermmm I would say it depends on the patient. So if I'm gonna talk about oral intake, so the patient started on oral intake and then we see how they progressed after one year I would say the PSS. It provides more details about oral intake. The*

FOIS can be vague. Because I don't know what specific food the patients are having. But the PSS can give me that. For tube dependent patients I would go with FOIS.

Another clinician agreed with the same notion, by saying:

D-R: Well, I think the FOIS would give us more information about changes over time. Because we know if the patient has changed in different levels, for example moving from tube dependent to oral intake or vice versa.

While one clinician thought that the FOIS would better:

SLT-L: The first one [FOIS], it's clearer. The second one [PSS] has missing items.

The missing items she is referring to are regarding fluid intake.

- **Communication with others**

The final sub-theme was the use of scales to communicate with others. Clinicians believed that the scales would not only be useful as an outcome to assess dietary restrictions, but also to support communication with others, either other healthcare professionals (HCPs), caregivers, or the patients themselves. Again, one clinician thought that the use of FOIS would facilitate communication with other HCPs because it provides information on the method of intake, whether oral or enteral:

SLT-F: because in the FOIS there are details about the method of intake. The PSS, not a lot. Only one. PSS is one level tube fed. The FOIS has many levels. So if I'm to use one I'd use the FOIS.

Another clinician thought that because the FOIS is more general, it could be easily communicated to the patients themselves or their caregivers:

D-M: the first one is very general. It gives an overall idea. I know who to talk to … I feel like if I worked in an outpatient department, the first one would give me an idea of who to talk to. The wife or the patient. Who's cooking?

On the other hand, others thought that the PSS would be easier for communicating with other clinicians from the same or different disciplines. One clinician specified that the scale can be easily communicated with dieticians, saying:

> *SLT-Y: Personally, I think I'll choose the second one [PSS]. Because it's more suitable for diet. Because we work with dieticians, so this gives an idea of what consistency the patient is having. So when we give them this scale [PSS] they'll know what type of food the patients are having.*

Another clinician specifically mentioned communication with nurses, by stating the importance of providing the details of food consistencies to them:

> *D-R: I think this one [PSS] is really good for communicating with other HCPs, especially the nurses. For in-patients, this is really important as they have the most contact with the patients so they can be aware of exactly what they can or can't have.*

Similar thoughts were communicated by others, for example:

> *SLT-Sh: With this one [PSS] I think everyone can follow-up easily with the patients, because just by looking at the scale you can tell what consistencies the patients can tolerate. The FOIS is good, but if another SLT would assess the patient and see for example level 4, single consistency. What is this single consistency? It can be anything. Both scales are useful, and can give information missing by the other.*

> *SLT-D: I think it will add. I think it will be something easy to read by someone who is not an expert in dysphagia. Even family members can understand this scale.*

Distribution of the Performance Status Scale – Normalcy of Diet scores over three time points in patients treated with (C)RT

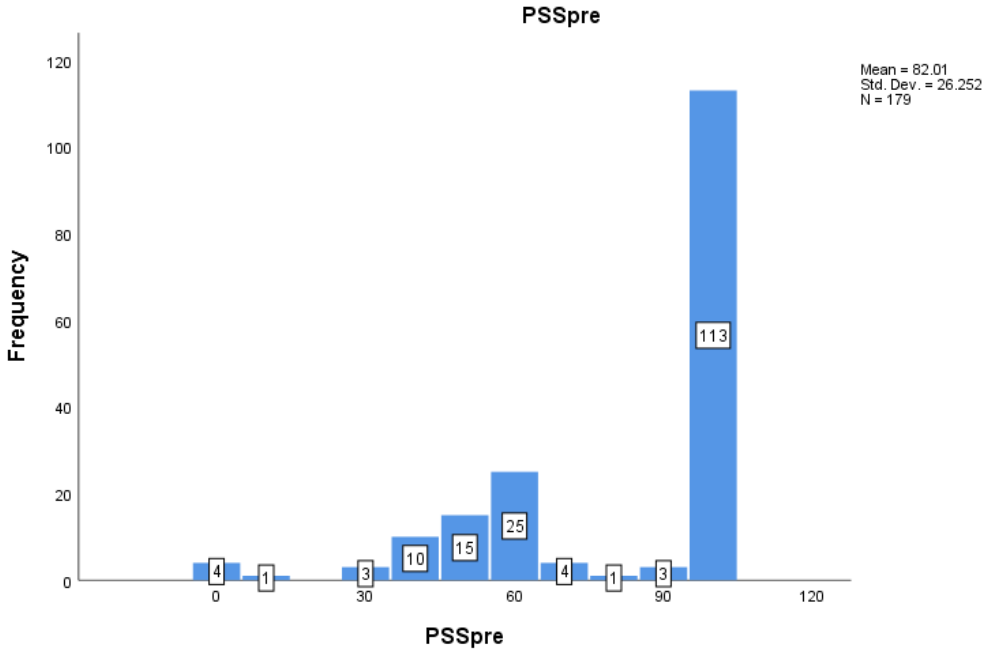
As there were some difficulties identified in the PSS-NoD categories (Theme 1, Comprehension – categories sub-heading), in this section I aim to report on the distribution of the PSS-NoD scale scores over three different time points in patients treated with (C)RT. This is a secondary analysis of a previously collected data for a different study (Patterson, 2010). Ethical approval was previously obtained for this study, and it was not deemed necessary to apply for a new approval for the secondary analysis.

In total, there were n = 239 HNC patients treated with radiation with or without chemotherapy. The mean age (SD) was 63 (11) years. Males accounted for 80% of the sample. Regarding tumour site: 39% of the sample were patients with oropharyngeal cancer, followed by 34% patients with larynx cancer. The rest of the sample were patients with hypopharyngeal (13%), unknown primary (9%) and nasopharyngeal cancer (4%). Regarding treatment modality, 56% of the patients received CRT, while 34% received RT only.

Graphs were produced using SPSS version 24.

Figure 14 displays dietary restrictions at baseline, when most patients have a normal diet (scored at the highest end of the scale). Only some dietary restrictions are reported as treatment has yet to start.

Figure 14 Distribution of PSS-NoD scores at baseline pre- (C)RT treatment



In Figure 15, patients are shown to have more diet restrictions. In this distribution, none of the patients were shown to be in categories 70 (raw carrots, celery) and 80 (All meat). Similar observations can be seen at twelve-months post-treatment for the (All meat) category, with only two patients being scored for category 70 (Figure 16).

Figure 15 Distribution of PSS-NoD scores at three months post (C)RT treatment

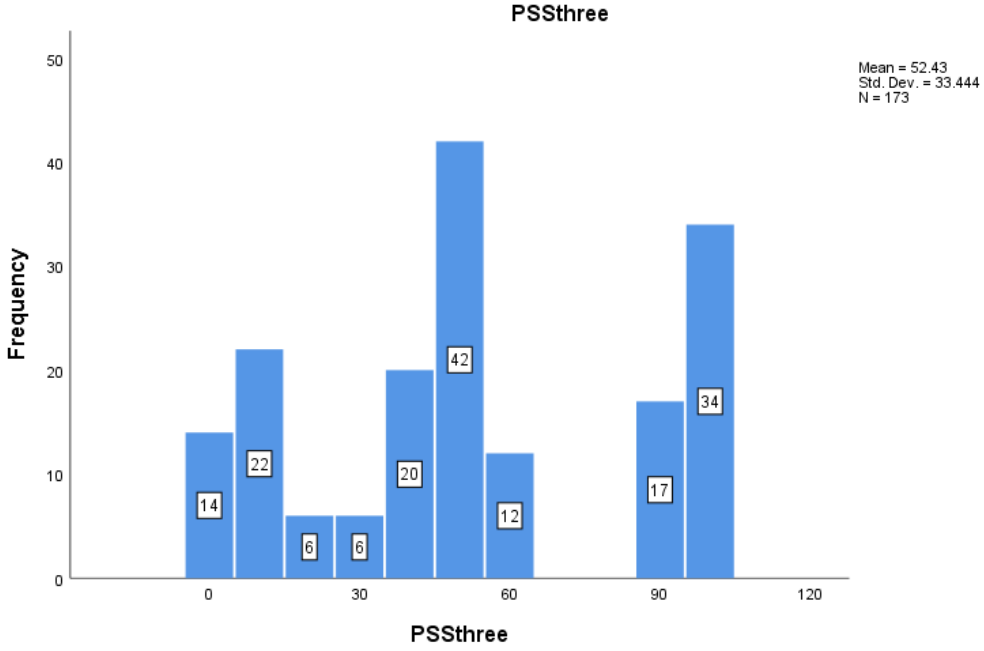
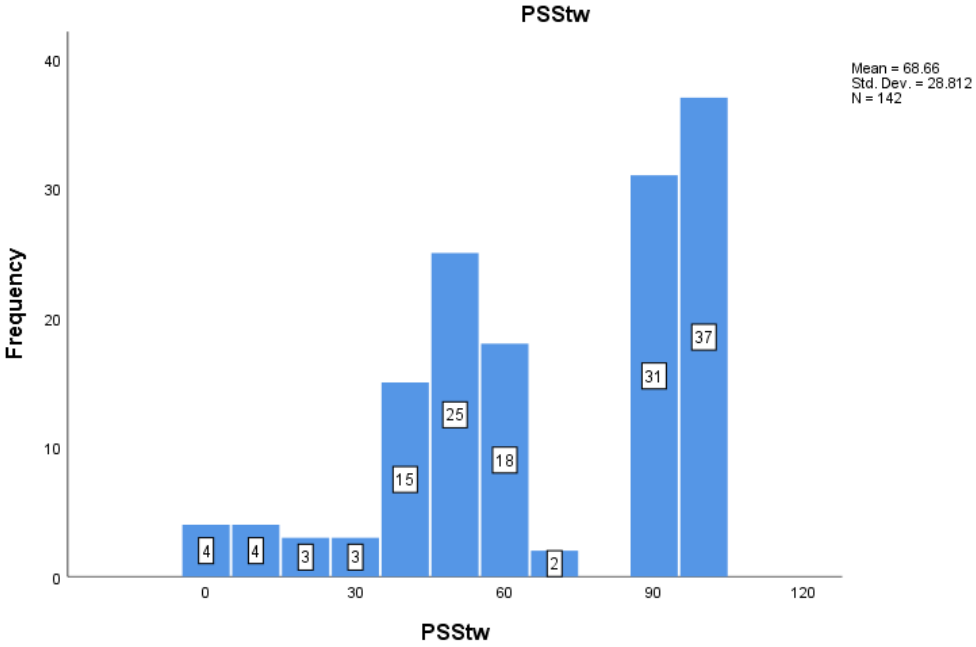


Figure 16 Distribution of PSS-NoD scores at twelve months post (C)RT treatment



5.5 Discussion

The cognitive interviews conducted with clinicians who work or have worked with patients with HNC in Kuwait indicated that they accept and appreciate the value of implementing diet scales in clinical practice. However, they also uncovered some issues in terms of the comprehension and response aspects. No issues were identified in terms of retrieval and judgement; however, for the latter, issues were mainly caused by the limitation of what information case vignettes offered.

Cognitive interviews aim to gather information about the questionnaire/tool being tested and to identify any problems specific to the scale. Importantly, cognitive interviews are not a form of validity testing, nor can they resolve problems identified, which need to be resolved through further testing (Willis, 2005). This type of interviewing is usually used to improve questionnaire design (Willis, 2005). However, in some cases they can also be used to examine clinicians' comprehension of key concepts related to practice. For example, Smith and colleagues (1992) studied physicians understanding of key concepts related to 'the cause of death' by utilising cognitive interview design through the use of vignettes. The authors found that there are some misunderstandings about the key terms, and suggested that there is a lack of training in filling out death certificates.

Here, cognitive interviews identified some problems in the category descriptions of the PSS-NoD, certain issues related to its scoring and in identifying the most representative PSS-NoD category. These highlight difficulties that clinicians may encounter while using the scales.

The findings of this study suggest that a minority of clinicians failed to fully comprehend PSS-NoD instructions. Before administering and implementing the scale, the instructions could be written in collaboration with other clinicians to avoid potential confusion. Notably, some confusion was evident regarding certain categories, especially the category 'All meat' on the PSS-NoD. Remarkably, no previous studies utilising the PSS-NoD as an outcome measure reported encountering similar issues with this category. These difficulties could be attributed to the scale being unfamiliar to participants, requiring more time to become acquainted or the use of case vignettes rather than real-life scenarios (Converse et al., 2015). Nevertheless, the results of the secondary data analysis of the score distribution

across three time points (baseline, three and 12 months post treatment) indicate that the selection of the 'all meat' category is extremely rare, as has been noted when looking at data reported in other studies (Kamal et al., 2019; List et al., 1996; List et al., 1997). However, no firm conclusions can be drawn from these findings. A larger dataset is required to identify the most commonly endorsed PSS-NoD categories, and the scale may need to be adjusted/modified to eradicate unused categories. The investigation of score distribution is especially important when assessing changes over time, as it is vital not to overestimate or underestimate these changes, especially when some of the categories are not being utilised.

A further consideration is the distribution of scale categories and the potential for them not to be equally weighted. For example, a 10-point difference between 'warm liquids' (10) and 'cold liquids' (20) is not reflective of the 10-point difference between 'dry bread and crackers' (60) and 'soft chewable food' (50). These issues may result in compromise or inaccuracy in establishing the minimal clinically important difference (MCID – the smallest change perceived significant by the patients; Copay et al., 2007). Altering the scale categories is a major change which would require considerable additional testing and research.

The participants in this study indicated no information retrieval issues regarding food consistency and texture, being also able to retrieve the information they needed from memory, or from the available data at hand. When faced with unfamiliar food items, the clinicians checked the food glossary and gallery. This was observed and written in field notes, and sometimes verbalised during the 'think aloud' process. However, two of the clinicians skipped the unfamiliar food items and relied on their knowledge of familiar items. This could be a good strategy in clinical practice; however, this option may not always be available or reliable as most of the time the scoring of the scales takes place while interviewing the patients. Additionally, clinicians may risk underestimating the difficulty of tolerated consistencies when using this method. The addition of the food gallery and glossary was found to be useful, and the use of such methods may need to be considered in clinical practice, especially in culturally diverse populations.

Although the local diet differs from that described in the scale, adding more examples may be useful to ensure that the scale is more relevant to the different textures of the locally

consumed food items. For example, white rice was added as an example of the score (50) 'soft chewable food' in a study conducted in Japan as it is a primary food component there (Kondo et al., 2018).

Despite the absence of some information that clinicians believed would be essential for rating the scales, the clinicians found it possible to base their judgement based on the available information and rate both scale.

In terms of response, clinicians occasionally had issues with linking their opinion of the diet onto the patient's diet and the categories. Some clinicians reported that scoring the FOIS was easier than scoring the PSS-NoD as the former is divided into two sections; however, other clinicians preferred the PSS-NoD as it provides examples, which makes the scoring process quicker.

Opinions about scales

Most clinicians believed that the addition of the scales in clinical practice would be useful; some clinicians preferred one scale over the other, whereas other clinicians believed that both scales are complementary to one another, as each scale provides a different perspective. The FOIS scale considers patients' oral intake status with a general focus on the food consistencies that they can manage. In contrast, the PSS-NoD indicates the complexity of the food consistencies that patients can manage, regardless of their tube dependency status. The clinicians also based their preferences on the ability of the scale to capture changes over time. Clinicians' preference of the FOIS was solely based on the patients' oral intake status at the time of assessment, assuming that because FOIS categorises these patients on the basis of their tube dependency, it would be more reflective of the changes. On the contrary, clinicians who reported a preference of the PSS-NoD is because it is more concerned with food textures, which may be more reflective of the changes in oral intake difficulty. Clinicians also believed that the use of either scale would be beneficial in communicating with other healthcare professionals or the patients and their caregivers.

Incorporating diet scales as an outcome measure

There are several benefits to implementing dietary restriction scales in clinical practice. The scales can be completed by any healthcare professional without any special training. This was also evident from the results of this study, as most clinicians were novices in either or both scales. It has been reported that the PSS-NoD had the most complete data in the first year of treatment and recovery owing to its ease of use and non-invasive nature (Patterson et al., 2014), making it a suitable scale for clinical implementation because of its widespread acceptance by patients and clinicians. Diet scales have a strong-to-moderate correlation with PROs (Pedersen et al., 2016; Speyer et al., 2011) and a moderate correlation with other outcome measures such as instrumental assessments and a measure of swallowing performance (100 mL Water Swallow Test [WST; which will be described in Chapter 6]; Pedersen et al., 2016). Because the FOIS and PSS-NoD are very highly correlated (Kamal et al., 2019; Zuydam et al., 2020), the FOIS is also expected to be correlated with instrumental and clinical assessments. Despite such high correlation, the two diet scales offer complementary information to that provided by PROs and clinical and instrumental assessments (Khan et al., 2015; Zuydam et al., 2020).

It is important to acknowledge that dietary restrictions are multifactorial and may not always be attributed to or caused by dysphagia. Swallowing-related factors such as xerostomia, taste changes, pain and dental extractions are some of the factors that contribute to changes in dietary habits (Patterson et al., 2014; Zuydam et al., 2020). These important factors are not included in diet scales and therefore need to be explored by clinicians to understand the nature and cause of the dietary restrictions. The findings from this chapter indicate that there is an individual preference of which scale to use in clinical practice, therefore, both scales will be part of the Swallowing Outcomes Package and as both scales provide valuable information, the choice of which scale to use will be for the clinician to determine.

5.6 Limitations

This study has several limitations that need to be addressed. The sample size is modest; however, a small sample size is expected with cognitive interviews owing to the nature of the valuable data yielded by this method. It is recommended to include approximately 5 to

15 participants in an interview round (i.e., before reviewing and interpretation; Willis, 2005). In the present study, this criterion was fulfilled. However, no further cognitive interview rounds and testing were conducted. In addition, the results of this study are based on a small sample in one country and therefore may not be representative of other practices worldwide. In the present study, only SLTs and dieticians were included; therefore, it lacks the perspective of other healthcare professionals involved in HNC management, who may collect data using either scale, for example, nurses. The case vignettes were designed to include a wide range of diets and oral intake methods; however, they were limited in what they could offer and also had some missing information as reported by the participants. Therefore, vignettes cannot perfectly replicate real-life situations.

5.7 Clinical implications

Diet scales are useful tools for capturing the degree of dietary restrictions. When used in conjunction with PROs (e.g., the MDADI, as suggested for this package) they offer distinct information of the type of functional limitations. Because both FOIS and PSS-NoD have good patient and clinician compliance, they can be easily incorporated into clinical practice. The scales provide information on changes over time and can act as monitoring tools to capture the effect and effectiveness of HNC treatment and swallowing rehabilitation interventions. As suggested by the participants in the present study, FOIS and PSS-NoD offer a common means of communication among healthcare professionals, patients and their caregivers. Aside from being used as part of the Swallowing Outcomes Package, the diet scales offer valuable information and can be used during treatment to identify changes in diet, and to respond accordingly.

5.8 Implications for future research

The FOIS and PSS-NoD are commonly reported in HNC studies and in clinical practice; investigating what constitutes an MCID for both scales is an important step towards increasing the utility of these tools. However, before such an investigation, it is important to clearly understand how the scores are generated and whether all scores are reasonable and are being utilised sufficiently, especially for the PSS-NoD. Future studies should also consider the perspectives of other healthcare professionals on the scales.

Chapter 6: Swallowing Outcomes Package: A Clinical Measure of Swallowing Performance

This chapter describes the third component of the Swallowing Outcomes Package. In Chapter 4, I reported on a dysphagia-related quality of life (QOL) outcome, the MD Anderson Dysphagia Inventory (MDADI). Chapter 5 described another dimension of swallowing, concerning dietary restrictions, and I reported on two diet scales, the Functional Oral Intake Scale (FOIS) and the Performance Status Scale – Normalcy of Diet (PSS-NoD). In this chapter, I will describe a clinical test for swallowing performance, the 100 mL water swallow test (100 mL WST). This test has been described in head and neck cancer (HNC) literature. It is a simple, universal and well-tolerated clinical test, but further work is indicated to explore the interpretation of this test for clinical and research purposes.

6.1 Literature review

It is well documented that swallowing fluctuates and changes during and after the course of HNC treatment. Longitudinal swallowing evaluations are of immense practical benefit to monitor these changes over time. As reported in the previous chapters, patient-reported outcomes (PROs) such as the MDADI and dietary restrictions scales (e.g., FOIS or PSS-NoD) are useful and sensitive for recording changes over time. These measures capture swallowing related QOL and oral eating restrictions. However, another important dimension of swallowing is the measurement of swallowing impairment. The 100 mL WST measures swallowing impairment by testing swallowing performance (ability). The 100 mL WST is a timed test that yields three swallowing parameters: swallow volume (calculated as mLs swallowed divided by number of swallows), swallow capacity (mLs swallowed divided by time taken) and swallow speed (time taken divided by number of swallows; Hughes and Wiles, 1995; Patterson et al., 2009). This test was validated against Videofluoroscopy in patients with dysphagia related to neurological diseases (Wu et al., 2004). It was then validated against Fiberoptic Endoscopic Evaluation of Swallowing (FEES) for patients with HNC (Patterson et al., 2009; Patterson et al., 2011). Only swallow capacity was deemed to be sensitive for detecting changes over time (Patterson et al., 2011), and therefore the current study will report on swallow capacity only. It is worth noting that

swallow volume and capacity have strong correlation too, so swallow capacity can act as a quick summary measure on performance.

It has been reported that healthy individuals have a mean WST capacity of 20 mL/sec, whereas at baseline, patients with HNC had a mean WST capacity of 17 mL/sec (Patterson et al. 2009; Roe et al., 2016). Completing a swallow in a shorter period of time requires coordination and shorter transit times, therefore, higher WST scores indicate a greater swallow performance (Pedersen et al., 2016). Swallow capacity was affected by tumour stage, while patients with T3-T4 tumours had significantly lower swallow capacity ($p = 0.02$) in comparison with patients with T1-T2 tumours. However, the site of tumour was not found to have an impact on WST capacity. In addition, swallow capacity was found to be affected by patients' sex and age, with males and younger patients recording better swallow capacity (Patterson et al., 2009). The 100 mL WST demonstrated responsiveness to changes from baseline (17 mL/sec) to three (12 mL/sec) and twelve months (14 mL/sec) post-treatment, with a significant deterioration at three months and then significant improvement at one year, though without a return to baseline status (Patterson et al., 2011; Roe et al., 2016). A significant decline was also observed at six years post-treatment in comparison with one-year results (Patterson et al., 2018). Despite affecting WST capacity at baseline, patients' sex and age were not found to be predictive of changes across post-treatment time points (three, six and twelve months post-treatment; Patterson et al., 2011).

6.1.1 Clinical swallowing evaluations

The clinical swallowing evaluation (CSE) is a valuable early step in dysphagia assessment (Patterson and Wilson, 2011). CSEs help clinicians detect and determine swallow safety and efficiency, decide if further instrumental assessments are warranted, weigh patients' risk for dysphagia and identify potential causes for dysphagia (Garand et al., 2020; Logemann, 1998; Patterson and Wilson, 2011). CSEs are criticised for having poor sensitivity and specificity for detecting aspiration. Throat clearing or coughing during or after swallowing trials, in addition to voice changes, are clinical indicators of the presence of aspiration, with a sensitivity of 87% and specificity of 72% (Hassan and Aboloyoun, 2014; Logemann, Veis and Colangelo, 1999). Evidence supports the utility of WSTs in detecting aspiration in addition to the previously mentioned clinical signs (Brodsky et al., 2016; Chen et al., 2016;

Bours et al., 2009). It has been suggested that combining consecutive sips (i.e., drinking large quantities of water [90–100 mL] continuously, which has a high sensitivity [91%]) with single sips of small and larger volumes (1–20 mL) increases the specificity for detecting aspiration (90%; Brodsky et al., 2016). Failing a WST should trigger the need for an instrumental evaluation to determine or rule out aspiration. When examining the ability of the 100 mL WST to detect aspiration pre- and post-(chemo)radiotherapy (CRT) treatment for patients with HNC, it was found that the test had a sensitivity of 80% and specificity of 77% at pre-treatment, which declined to a sensitivity of 67% and specificity of 53% at 12 months post-treatment (Patterson et al., 2011). The relatively low sensitivity and specificity suggest that the 100 mL WST cannot replace the role of instrumental assessments, but it can be used as an adjunct to CSE to assess swallow efficiency and to enable a more thorough data synthesis to decide on the next steps of management. The 100 mL WST can be easily incorporated into any CSE, is well tolerated by patients, and can be repeated over time.

Patients with HNC require long-term follow-up; the 100 mL WST is simple to implement and is applicable over a wide geographic distribution; as it is not a culturally sensitive test and requires minimal training and can be performed by any healthcare professional or the patients' themselves, it can also be performed via telehealth; therefore, the test has particular appeal for use in the context of HNC, and it can be used to quantify outcomes and to enable longitudinal comparisons. The 100 mL WST has been proved to be sensitive to changes over time (Patterson et al., 2011; Roe et al., 2016). However, an important dimension of the 100 mL WST has yet to be identified; it is well recognised that in the interpretation of changes in health outcomes, it is important to understand what changes represent and how meaningful such a change is from the patient's perspective. Statistically significant changes in health outcome data may not be equated with clinical significance. Therefore, this study aims to investigate the minimal clinically important difference (MCID) for the 100 mL WST.

6.1.2 The minimally clinically important difference

The MCID is defined as 'the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in patient's management' (Crosby, Kolotkin and

Williams, 2003). An alternative utilitarian definition is 'the smallest change that is important to patients' (Copay et al., 2007). Three methods of MCID determination are described: distribution based, anchor based and the Delphi method.

Distribution-based methods rely on the statistical properties of the outcome measure being investigated (McGlothlin and Lewis, 2014). In this method, the change of the outcome measure is compared to a measure of variability (Copay et al., 2007). It is based on the statistical characteristics of the sample. There are several approaches to determine the distribution-based MCID, for example: the standard error of measurement, the effect size and the standard deviation approach, with the latter being the most commonly used method (Copay et al., 2007; Maredupaka et al., 2020). The distribution-based methods have some inherent limitations as these are purely statistical and may not reflect clinical significance. Moreover, the patient's perspective of change is not considered in these approaches. Therefore, it is not recommended to depend solely on MCIDs generated by distribution-based methods, rather, these should be considered as an adjunct to anchor-based methods (Copay, et al., 2007; Maredupaka et al., 2020; Rai et al., 2015).

On the other hand, the anchor-based method compares the changes in the outcome measure being tested to an external relevant criterion, an 'anchor' (Rai et al., 2015). A common characteristic of all anchor-based methods is the use of an independent external criterion; however, many differences remain between the type of anchor being used, the employed methods for calculating the MCID and the type of analysis (cross-sectional or longitudinal; Copay et al., 2007). In general, longitudinal analyses are preferable over cross-sectional analyses, as the former are associated with change (Crosby et al., 2003). However, cross-sectional analyses are common (Hutcheson et al., 2015) as the data can be easily obtained, in comparison with longitudinal data. Yet, MCIDs based on cross-sectional analyses may not be reflective of an actual change and patients may differ in other key variables besides their outcomes on the measurement being tested (Crosby et al., 2003). On the contrary, longitudinal analyses are more challenging to perform as these require data collected on a long period of time, yet they are more reflective of changes over time from patient's perspective (Crosby et al., 2003; Rai et al., 2015).

Regarding the choice of the clinical anchor, some studies have used a disease-related criterion as an anchor, for example by comparing patients with different disease severities

or diagnoses. An alternative anchor is a non-disease-related criterion (e.g., impact of life events, such as loss of a loved one or loss of job; Crosby et al, 2003). Reliance on objective clinical anchors is not widely reported (Copay et al. 2007), while a global rating assessment is customary (Copay et al., 2007; Crosby et al., 2003; Rai et al., 2015). Global questions are criticised due to their unknown reliability and validity. In this type of anchor, patients are asked a specific question (e.g., compared with your swallowing ability before treatment, how would you rate your swallowing now?). Patients' responses can be categorised as worse, unchanged or better and these responses are assigned to transitional groups, or anchors that would be based on a typical 5-point scale (e.g., substantially worse, somewhat worse, unchanged, somewhat better, substantially better; Copay et al., 2007; Maredupaka et al., 2020). As the answer to the global question rely on retrospective self-report, it may be affected by recall bias (i.e., the patient's remembrance of baseline status may be inaccurate).

Anchor-based methods are not without limitations. Anchor-based methods are limited by the choice of the clinical anchor, and as a result, choosing different clinical anchors may yield different MCIDs. Moreover, the statistical distribution of scores within the clinical anchors may also influence the results (Copay et al., 2007; Rai et al., 2015; McGlothlin and Lewis, 2014).

A less commonly used method is the Delphi method or consensus-based method. In this method, a group of experts in the field provide impartial opinions on what constitutes a meaningful change. This process is repeated until an agreement is reached (McGlothlin and Lewis, 2014). However, this method is criticised as not being reflective of what change is important from patient's perspective (Rai et al., 2015; Revicki et al., 2008). Therefore, the Delphi method can be a useful adjunct to finalise the MCID rather than solely depending on it to generate an MCID (Rai et al., 2015; Revicki et al., 2008).

In summary, MCIDs generated from anchor-based methods are more representative of patient's perspective, and therefore, should be assigned the most weight. MCIDs generated by distribution-based methods should be used as complementary information to the MCID generated by anchor-based methods. It is recommended to use multiple methods to estimate the MCID, and then triangulate the values to get a single value, or a small range of values (Revicki et al., 2008; Maredupaka et al., 2020), while the Delphi-method can be a

useful adjunct to finalise the MCID values (Rai et al., 2015; Revicki et al., 2008; Maredupaka et al., 2020).

6.1.3 MCID of swallowing outcomes measures

Hutcheson and colleagues (2015) investigated the MCID cross-sectionally (between group analysis) for the MD Anderson Dysphagia Inventory (MDADI) using distribution-based and anchor-based methods. The authors concluded that a 10-point difference is associated with clinically meaningful differences in swallowing function based on different disease-related criterion (i.e., aspirators vs. non-aspirators, tube-dependent vs. no tube; non-oral vs. oral; Hutcheson et al., 2015). The study has several strengths including: a large sample size (n= 1136), using three disease-related clinical anchors (oral intake status, aspiration status, and tube-dependency status). However, it is unknown if patients MDADI scores differed in key variables such as between different tumours sites, treatment type, and time of completions, and patients age and sex which may influence the outcomes. Moreover, the findings of the study may not be reflective of actual changes due to the nature of the study design. Regardless, the findings allow comparisons between different groups of patients, but does not provide information on longitudinal changes. The authors also reported that a 10-point difference of the PSS-NoD detects a medium effect size (Cohen's d = 0.599), suggesting that it equates to a 'between-group' meaningful change (statistically driven). As reported previously in Chapter 5, the process in which the developers of the PSS-NoD (List et al., 1990) derived their category descriptions and scores associated with these descriptions is unknown. In addition, changes between the PSS-NoD categories may not be equal between all categories (e.g., cold liquids [10] and 'warm liquids [20], 'soft chewable foods' [50] and 'dry bread and crackers' [60]). Therefore, some considerations are needed before depending on the 10-point difference as an MCID for the PSS-NoD.

A previous study by Arullendran and Patterson (2016) investigated the MCID for the 100 mL WST longitudinally, using both anchor-based and distribution-based methods. The authors used the PSS-NoD subsection as a clinical anchor and the half standard deviation for the distribution-based method. The authors categorised the PSS-NoD results into three categories (predominantly liquid diet, predominantly soft diet and near normal diet). The transition between groups resulted in five clinical anchors. The MCID was calculated for a sample of n = 121 patients receiving (C)RT treatment with a majority of laryngeal cancer

patients (n = 52). As the sample size was smaller, the authors were not able to capture different categories of change. It was found, that the MCID is 5 – 7 mL/sec for swallow capacity. However, it is unclear which time points were used to determine the MCID (e.g., baseline and three months, or baseline and twelve months). Moreover, the MCID for the distribution-based method was determined by pooling data across three time points. Typically, for longitudinal studies, the MCID based on distribution-methods should be determined based on baseline data. The PSS-NoD scale is a practical scale for assessing dietary restrictions, however, it is a clinician-rated scale and may not be reflective of patient's perspective. Therefore, the present study aims to build upon the previous findings using a larger data set and a patient-reported outcome as a clinical anchor.

6.2 Rationale and aims

Measuring the MCID is an important metric of clinical significance as opposed to statistical significance. Moreover, as the test is currently being used in national and international clinical trials (Owadally et al., 2015; Petkar et al., 2016; Simon et al., 2018) and feasibility studies (Govender et al., 2020; Wells et al., 2016), understanding how to interpret the changes in the test is crucial. Therefore, this study aims to:

Aim 1: Determine the distribution-based MCID for the 100 mL WST.

Aim 2: Determine the anchor-based MCID for the 100 mL WST.

Mean change.

Receiver Operator Characteristics (ROC) analysis.

6.3 Materials and methods

This study is a secondary analysis of a prospectively collected data from three UK databases collected by: Newcastle University Hospitals Foundation Trust, South Tyneside and Sunderland Trust and The Royal Marsden NHS Foundation Trust. The databases include: 1) research database for swallowing outcomes over time in HNC patients treated with 3D radiotherapy (RT) and Intensity-Modulated Radiotherapy (IMRT) (2006 - 2009), 2) regional audit on swallowing outcomes comparing feeding tubes (reactive nasogastric tube and prophylactic gastrostomy) in HNC (2009 - 2013), 3) routine clinical outcome data for HNC patients (2016 onwards). The databases excluded patients who were unlikely to have dysphagia and were small in number (salivary gland and sinonasal tumours), patients who

were neck breathers i.e., laryngectomy or tracheostomy (due to profound alterations to swallowing anatomy) -, palliative care patients, and patients with cognitive difficulties, unable to follow WST instructions. WSTs were collected at baseline, three, six-, and 12-months post treatment. For the purpose of this study, only baseline and 12 months data were extracted and the MCID was calculated for the change from baseline to 12 months, as studies show that swallowing significantly deteriorated from baseline to three months post treatment, however, significant improvement in swallowing was maintained from three to 12 months (Patterson et al., 2011). Moreover, the change from baseline to 12 months will include a variability of patients showing improvement, deterioration, and patients who remained the same. If all or the majority of patients were deteriorating, the MCID will be limited and only obtained for one direction of change (i.e. deterioration).

In this study a 'within-group' approach is used i.e., comparing longitudinal results within the same subject. This method is more recommended as it represents change. The MCID will be determined using the distribution-based method: the half standard deviation, and two anchor-based methods: the mean change, Receiver Operator Characteristics (ROC) analysis. The MDADI will be chosen as a clinical anchor, as it is based on patient's perspectives and previous research have shown that it correlates with the 100 mL WST. It is important to estimate the MCID from patient's perspective, and the MDADI will allow such perspective.

Scoring

Water Swallow Test

The test requires the individual to be seated upright and comfortably. Then, he/she will be asked to drink a previously measured 100mL of water from a cup 'a quickly as comfortably possible'. By observing the movement of the thyroid cartilage, the number of swallows taken is counted, in addition, a timer is set to start as soon as the water touched the lower lip and stopped when the larynx is rested after the last swallow; this is usually associated with other signs e.g., opening of the mouth, exhalation or phonation. If the individual coughs during the test, they will be asked to stop drinking immediately and the test will be terminated. Wet/gurgly voice and coughing during, and/or after swallowing are noted. Furthermore, any residual water will be measured using a syringe (Hughes and Wiles, 1996; Patterson et al., 2009). All units adhere to the same protocol.

As mentioned earlier, this study will report on swallow capacity, and it is calculated as:

Swallow capacity (millilitres per second = mL swallowed divided by time taken).

Higher scores indicate higher (better) performance. Patients unable to complete the WST are scored a zero.

The MD Anderson Dysphagia Inventory

The MDADI is a 20-item questionnaire, and it was thoroughly described in Chapter 4. In summary, the MDADI composite score is derived from averaging the scores of the 19 questions and multiplying them by 20 and that results in a range between 20 – 100, where 20 indicates low functioning (worse quality of life (QOL)) and 100 signifies high functioning (better QOL; Chen et al., 2001).

It is recommended to use the composite MDADI score as an endpoint when reporting the MDADI results, as it showed the least variability when compared with the other domains (functional, emotional, physical, and global; Hutcheson et al., 2015). Therefore, the composite MDADI score was used as a clinical anchor.

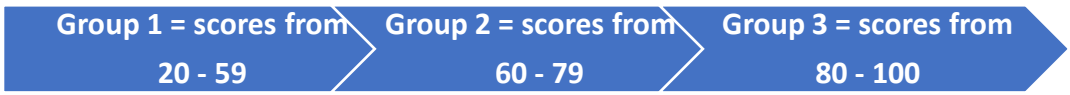
6.3.1 Distribution-based method

The MCID based on the distribution-based method was calculated based on the standard deviation.

6.3.2 Anchor-based method

Based on the suggested guidelines for calculating the MCID, it is recommended that the outcome measure being tested has a correlation of > 0.3 with the clinical anchor (Revicki et al., 2008). It has been reported previously that the 100 mL WST has a moderate correlation with the MDADI (Pedersen et al., 2016), making it an appropriate clinical anchor.

The composite MDADI score was grouped into three groups as follow:



These groups were based on categories made by (Goepfert, et al., 2017). Group one would represent patients with ‘poor’ function, whereas group two represent ‘adequate’ function, and finally, group three was ‘optimal’ function. The grouping of MDADI scores will

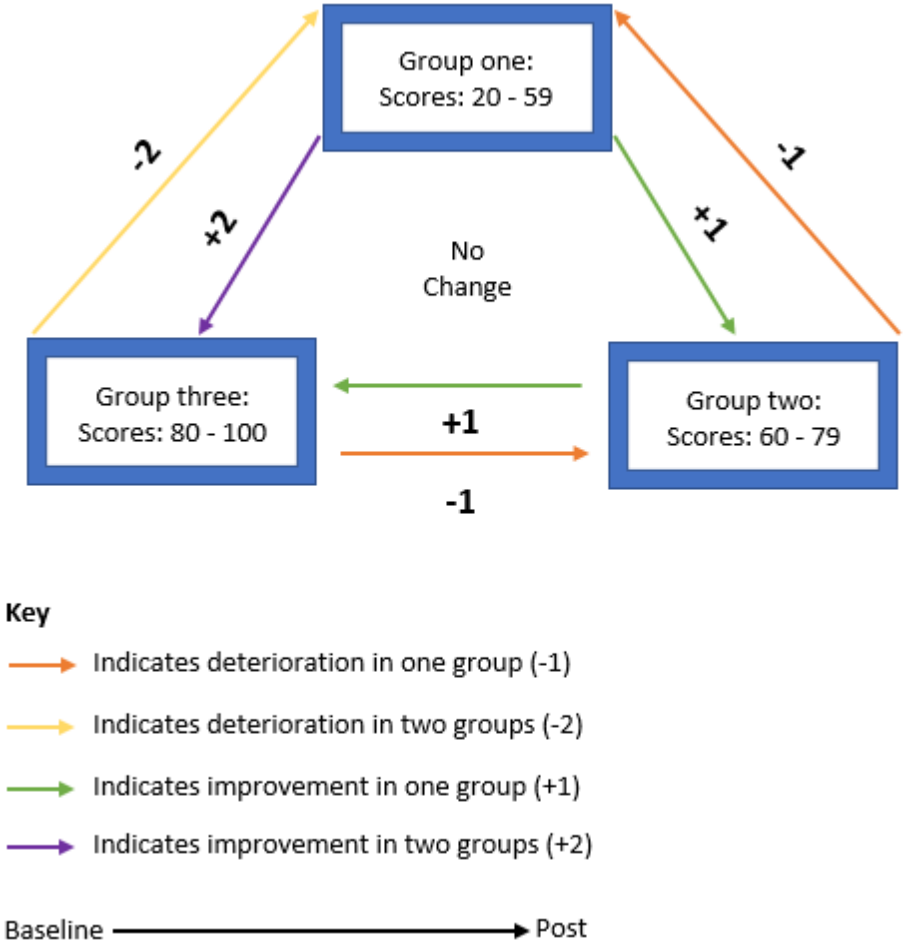
subsequently allow to determine the patients transition based on five anchors. The process will be explained below:

Based on this grouping of scores, five subgroups were established based on the change from baseline scores to 12 months scores and these subgroups will serve as the anchor points. For example, if a patient scored 80 to 100 at baseline, he/she will fall into group three, and then at 12 months follow-up, if he/she scores from 20 to 59, he/she will fall into group one. Based on this, the patient moved from group three at baseline to group one at twelve months, indicating a deterioration by two groups, hence the (-2) anchor point. All other anchor points are derived on the same basis of the previous example. Table 33 and Figure 17 below will further elaborate.

Table 33 Description of the anchor points used to indicate change from baseline scores to twelve months post-treatment scores

Categories	Description	Example
Anchor -2	Deterioration of 2 groups	Patient moving from group 3 to 1
Anchor -1	Deterioration of 1 group	Patient moving from group 3 to 2, or from group 2 to 1
Anchor 0	No change	No change
Anchor +1	Improvement by 1 group	Patient moving from group 1 to 2, or group 2 to 3
Anchor +2	Improvement by 2 groups	Patient moving from group 1 to 3

Figure 17 Description of the anchor points used to indicate change from baseline scores to twelve months post-treatment scores



6.3.3 Statistical analysis

Patients with one or more missing data from the MDADI and/or WSTs at baseline or twelve-months post-treatment were excluded from the analyses. Descriptive statistics were obtained for demographics (age and gender), and for the clinical characteristics (tumour site, tumour TN stage and the type of treatment). Mean scores and standard deviations for the WSTs and MDADIs at both time points were calculated and are also presented based on tumour site and treatment type. Floor and ceiling effects were also calculated for the baseline and 12-months MDADI and WST scores. A percentage of 15% and higher would indicate a floor or ceiling effect (De Vet et al., 2011). Typically, floor and ceiling effects are calculated as the percentage of patients obtaining the lowest or highest possible score, respectively. In this study however the MDADI floor and ceiling effects will be calculated based on the grouping of MDADI scores (i.e., groups 1, 2 and 3) as they are used to derive the clinical anchors reported in Table 33.

Prior to proceeding with calculating the MCID, the effect of age on the change in WST from baseline to 12 months was explored using Spearman rank-order (Spearman Rho). The effect of sex, tumour size (tumour size was aggregated into two groups: (T1 and T2) and (T3 and T4), site and treatment type on the change in the WST from baseline to 12 months were explored using the Kruskal-Wallis H test or the Mann-Whitney U tests as appropriate.

The MCID

The correlation between MDADI scores, clinical anchors, the WSTs and the change in WST from baseline to 12-month were calculated using the Spearman rank-order correlation.

Distribution-based method:

The half-standard deviation

The MCID was calculated as half of the standard deviation of the baseline WST score (Norman, Sloan and Wyrwich, 2003).

Anchor-based methods:

Mean change

The change in the 100 mL WST scores was calculated by subtracting baseline (pre-treatment) scores from post-treatment scores (12 months); (post-treatment – pre-treatment). The MCID was determined based on the patients categorised as deteriorating by one stage (anchor - 1) and patients categorised as improving by one stage (anchor + 1). Any patient with a value less than the cut-off is considered to be deteriorated while a value above the cut-off will be considered improved or unchanged. A one-way ANOVA test was used to explore the means of the different anchors, and post-hoc Tukey was performed to conduct a multi-group comparison between the clinical anchors and the mean WST difference in each group. This was confirmed with a Kruskal-Wallis H test to for a statistically significant difference between group anchors. The one-way ANOVA was used to determine the MCID as it generates means rather than ranking generated by the Kruskal-Wallis H test.

Receiver Operator Characteristics Curve

To perform a Receiver Operator Characteristics (ROC) curve analysis, it is necessary to dichotomize the outcomes. Therefore, patients were amalgamated into two groups according to the clinical anchor they fall into (Table 33):

1) Deteriorated: Includes patients in the deterioration anchors (-2 and -1).
2) Improved: includes patients in the unchanged anchor (anchor 0), and the improvement anchors (+1 and +2).

The ROC curve is constructed by plotting the sensitivity on the y-axis against 1-specificity on the x-axis for all possible cut-off values for the change in the 100 mL WST from baseline to twelve months. The most efficient cut-off value with regards of both sensitivity and specificity is related with the point nearest to the top left corner of the ROC curve (Kim, Park and Shin, 2014). An Area Under the Curve (AUC) of 0.7 to 0.8 is considered acceptable and an area of 0.8 to 0.9 is excellent (Copay et al., 2007).

6.4 Results

In total, 382 HNC patients' data were retrieved, only 211 patients had completed WSTs and MDADIs at baseline and 12 months and therefore were included in the analyses.

6.4.1 Demographics and clinical characteristics

The mean age was 60 ± 10 years, with males accounting for 83% of the sample. Approximately one half of the sample had oropharynx cancer, 59% had early tumours (T1 and T2) and 84% had non-surgical treatment. Table 34 provides detailed demographics and clinical characteristics information.

Table 34 Demographics and clinical characteristics of n = 211 patients included in the analysis for the MCID of the 100 mL WST

Patient characteristics	Category	N (%)
Age (years)	Range	24 – 87
	Median	60
	Mean ± SD	60 ± 10
Sex	Male	174 (83)
	Female	37 (17)
Tumour site	Oropharynx	119 (56)
	Larynx	49 (23)
	Unknown primary	15 (7)
	Hypopharynx	12 (6)
	Nasopharynx	10 (5)
	Oral	5
	Multi-site	1
Tumour T stage	1	53 (25)
	2	72 (34)
	3	35 (17)
	4	36 (17)
	x	15 (7)
Tumour N stage	0	65 (31)
	1	35 (17)
	2	104 (49)
	3	3
	Missing information	4
Treatment	Chemoradiotherapy	121 (57)
	Radiotherapy alone	56 (27)
	Surgery + (C)RT	26 (13)
	Surgery alone	8

6.4.2 Summary of outcome measures results

The mean MDADI and WST scores at baseline and twelve months were calculated and are presented in Table 35 and the distribution of scores are shown in Figures 18 - 21. Tables 36 and 37 present MDADI and 100 mL WST data based on different tumour sites and treatment modality.

Table 35 Mean baseline and 12-months MDADI and WST scores, and floor and ceiling effects n = 211

Variable	Mean ± SD	Min - Max	Floor (%)	Ceiling (%)
Baseline MDADI scores	85 ± 15	36 – 100	No (6)	Yes (70)
Twelve-months MDADI scores	72 ± 19	24 – 100	Yes (26)	Yes (36)
Baseline WST scores	18 ± 9	0 – 50	No (1)	No (1)
Twelve-months WST scores	15 ± 9	0 – 50	No (2)	No (2)

Floor and ceiling effects for MDADI scores are based on scores in MDADI groups 1,2 and 3.

Figure 18 Baseline MDADI scores for n = 211 patients included in the MCID analysis for the 100 mL WST

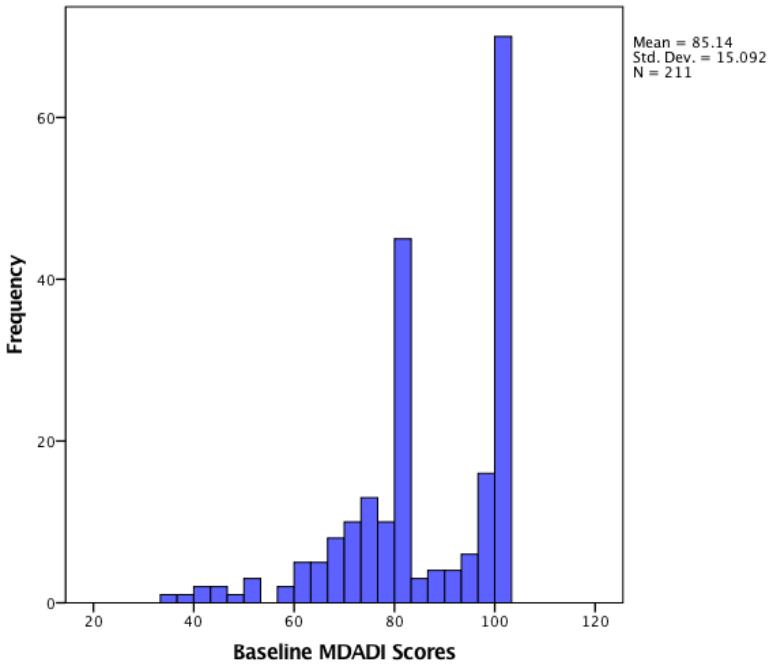


Figure 19 Twelve months MDADI scores for n = 211 patients included in the MCID analysis for the 100 mL WST

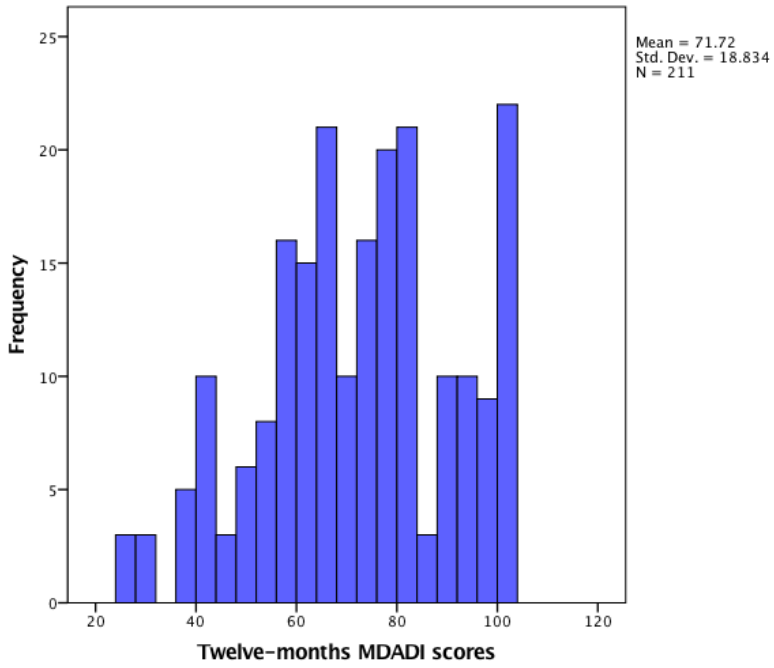


Figure 20 Baseline 100 mL WST capacity scores for n = 211 patients included in the MCID analysis for the 100 mL WST

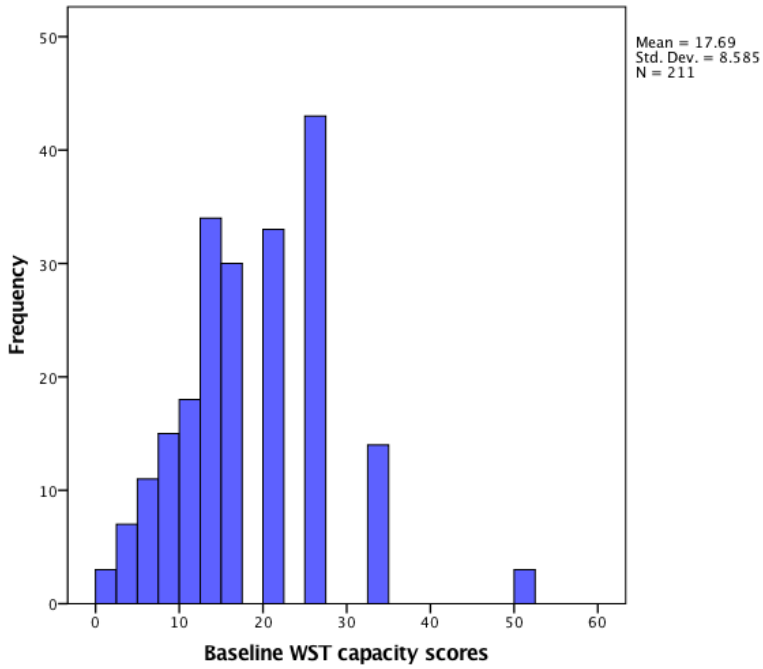


Figure 21 Twelve months 100 mL WST capacity scores for n = 211 patients included in the MCID analysis for the 100 mL WST

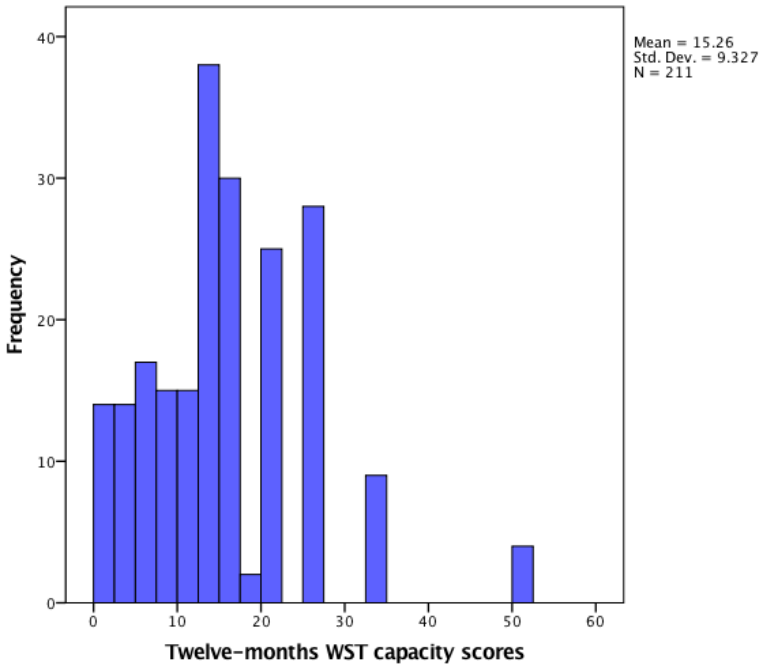


Table 36 MDADI and 100 mL WST scores based on tumour site for n = 211 patients included in the MCID analysis for the 100 mL WST

Tumour site	Variable	Mean ± SD	Min - Max
Oropharynx (n = 119)	Baseline MDADI score	86 ± 16	36 – 100
	Twelve-months MDADI score	70 ± 20	26 – 100
	Baseline WST score	18 ± 9	3 – 50
	Twelve-months WST score	15 ± 10	0 – 50
Larynx (n = 49)	Baseline MDADI score	84 ± 14	41 – 100
	Twelve-months MDADI score	78 – 18	24 – 100
	Baseline WST score	16 – 8	1 – 33
	Twelve-months WST score	15 – 8	2 – 33
Unknown primary (n = 15)	Baseline MDADI score	91 ± 10	79 – 100
	Twelve-months MDADI score	69 ± 21	26 – 100
	Baseline WST score	19 ± 8	8 – 33
	Twelve-months WST score	15 ± 10	0 – 33
Hypopharynx (n = 12)	Baseline MDADI score	75 ± 16	38 – 100
	Twelve-months MDADI score	73 ± 14	45 – 97
	Baseline WST score	14 ± 9	0 – 25
	Twelve-months WST score	14 ± 8	3 – 33
Nasopharynx (n = 10)	Baseline MDADI score	86 ± 12	66 – 100
	Twelve-months MDADI score	61 ± 12	41 – 79
	Baseline WST score	17 ± 6	9 – 25
	Twelve-months WST score	13 ± 6	3 – 25
Oral (n = 5)	Baseline MDADI score	96 ± 9	80 – 100
	Twelve-months MDADI score	74 ± 16	59 – 92
	Baseline WST score	23 ± 10	13 – 33
	Twelve-months WST score	19 ± 18	3 – 50
Multi-site (n = 1)	Baseline MDADI score	74	74 – 74
	Twelve-months MDADI score	69	69 – 69
	Baseline WST score	7	7 – 7
	Twelve-months WST score	7	7 – 7

Table 37 MDADI and 100 mL WST scores based on treatment type for n = 211 patients included in the MCID analysis for the 100 mL WST

Treatment type	Variable	Mean ± SD	Min - Max
Chemoradiotherapy (n = 121)	Baseline MDADI score	84 ± 16	36 – 100
	Twelve-months MDADI score	67 ± 18	26 – 100
	Baseline WST score	18 ± 9	0 – 50
	Twelve-months WST score	14 ± 8	0 – 50
Radiotherapy (n = 56)	Baseline MDADI score	86 ± 13	41 – 100
	Twelve-months MDADI score	78 ± 19	24 – 100
	Baseline WST score	17 ± 7	2 – 33
	Twelve-months WST score	16 ± 7	3 – 33
Combination of treatments (n = 26)	Baseline MDADI score	93 ± 11	72 – 100
	Twelve-months MDADI score	79 ± 18	41 – 100
	Baseline WST score	22 ± 8	5 – 33
	Twelve-months WST score	22 ± 13	0 – 50
Surgery (n = 8)	Baseline MDADI score	79 ± 17	46 – 100
	Twelve-months MDADI score	76 ± 23	42 – 97
	Baseline WST score	11 ± 6	6 – 25
	Twelve-months WST score	12 ± 11	3 – 33

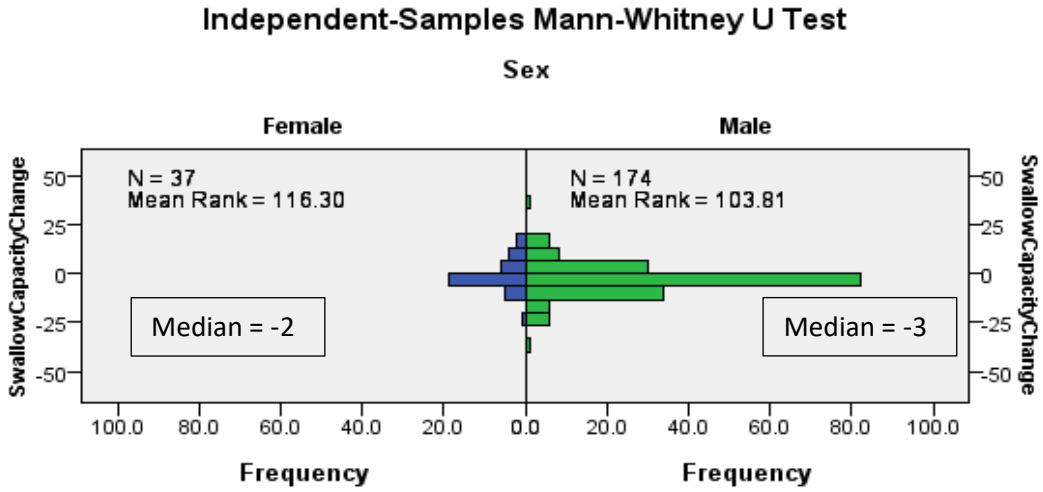
6.4.3 The effect of demographics and clinical characteristics on the change in 100 mL WST

Previous research has shown that age and sex affect swallowing performance at baseline, with men and younger patients having better performance (Patterson et al., 2009). In addition, treatment type also affected swallowing performance overtime with patients receiving multimodality having poorer capacity (Patterson et al., 2012). Therefore, it is important to explore if such relationship exists with the change in WST from baseline to 12 months to understand how this might affect the MCID calculation.

Age and sex

Neither age nor patients' sex had an influence on the change in WST. The correlation between age and the change in WST was not significant, rho = 0.04, *p = 0.5*. Furthermore, the Man-Whitney U-test indicated that the difference (based on the median change of the 100 mL WST) between males (-3 mL/sec) and females (-2 mL/sec) was not statistically significant, *U = 3,600, z = 1.1, p = 0.25.* Figure 22.

Figure 22 Distribution of the change in WST scores between males and females for n = 211 patients included in the MCID analysis for the 100 mL WST

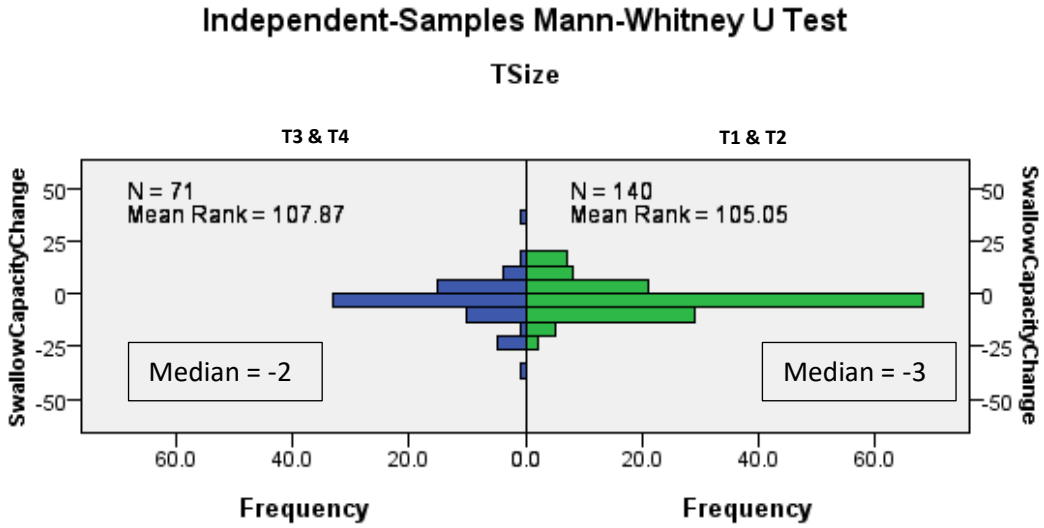


Tumour size and site

There was no statistically significant difference between tumour size and site on the change in WST. The Mann-Whitney U-test was run to determine if there were differences in the WST from baseline to twelve months between small and large tumour sizes. As assessed by visual inspection (Figure 23), the distribution of the change in WST scores were similar

in both groups. The median change in WST score for T1&T2 (-3 mL/sec) and T3&T4 (-2 mL/sec) tumours was not statistically significantly different, *U = 5,103, z = 0.31, p = 0.7.* Furthermore, a Kruskal-Wallis H test was conducted to determine if the change in WST capacity was different based on tumour sites. All but the multi-site tumour were included in the analysis to allow for group comparisons. Median change in WST scores based on tumour site were: oropharynx (-3 mL/sec), larynx (-1 mL/sec), Unknown primary (-4 mL/sec), hypopharynx (1 mL/sec), nasopharynx (-5 mL/sec), and oral (-2 mL/sec), the difference was not statistically significant $\chi^2(3) = 7.4, p = 0.17$.

Figure 23 Distribution of the change in WST scores between T1&T2 and T3&T4 tumour sizes for n = 211 patients included in the MCID analysis for the 100 mL WST



Treatment type

A Kruskal-Wallis H test was conducted to determine if the change in WST capacity was different based on treatment type. Median change in WST scores based on treatment type were: CRT (-3 mL/sec), RT (-2 mL/sec), combination of treatments (0 mL/sec), surgery (1 mL/sec), the difference was statistically significant between groups $\chi^2(3) = 8.1, p = 0.043$. However, pairwise comparisons were performed using Dunn's (1964) procedure with a Bonferroni correction for multiple comparisons. The post hoc revealed that the difference between the change in WST capacity, based on the adjusted p-values was not statistically significant between different treatment categories at a 0.05 significance level.

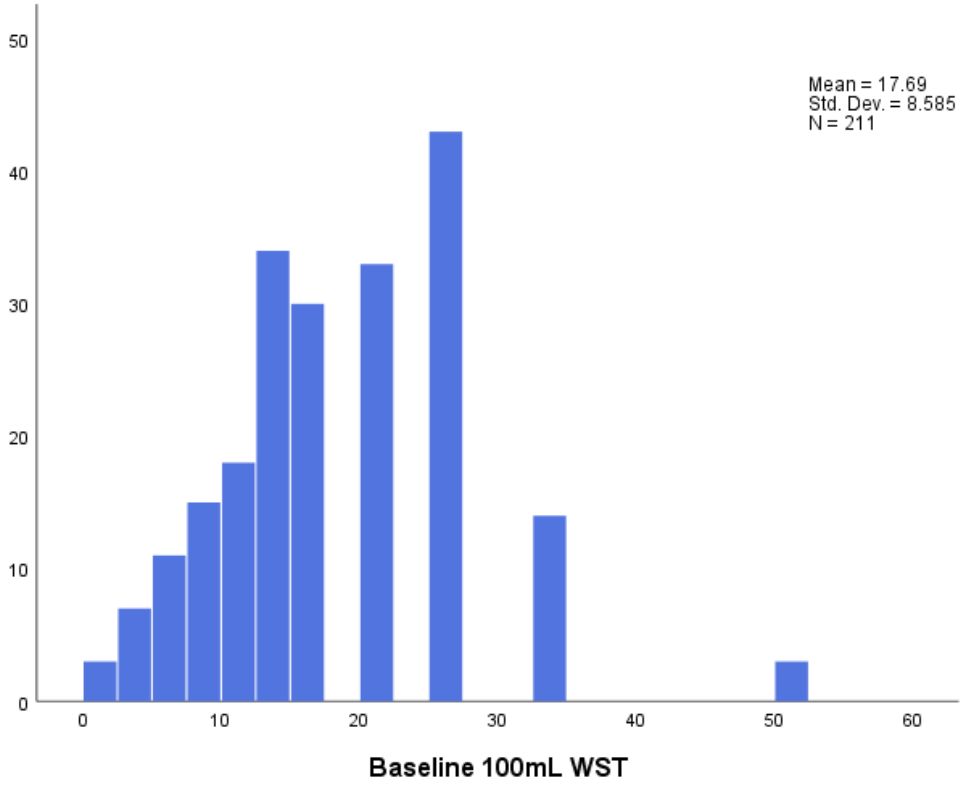
Summary of results

Based on the results, none of the investigated factors (age, sex, tumour site, size nor treatment type) had a significant impact on the change in WST from baseline to twelve months. Therefore, the MCID can reasonably be calculated for the whole cohort without exploring effects of the previously reported variables.

6.4.4 Aim 1: The Minimally Clinically Important Difference for the WST: Distribution based method using the half-standard deviation approach

The standard deviation of the baseline WST score is 9 (Figure 24), therefore, using the half standard deviation method, the MCID using distribution-based method is 5 mL/sec. Indicating that any change above this threshold is considered as an improvement.

Figure 24 Visualisation of the baseline 100 mL WST scores for n = 211 patients included in the MCID analysis for the 100 mL WST



6.4.5 Aim 2: The Minimally Clinically Important Difference for the WST using the anchor-based method

Following the suggested guidelines of choosing an anchor, the correlation coefficient was calculated for the MDADI, anchor points and the 100 mL WST scores. The correlation should be taken into consideration is the correlation between the change in WST and the clinical anchors. Results are presented in Table 38 below.

Table 38 Correlation between MDADI and WST, and MDADI anchors with mean baseline to twelve WST n = 211 included in the MCID analysis for the 100 mL WST

Variable		WST Capacity at baseline	WST Capacity at twelve months	Change in WST from baseline to twelve months
MDADI baseline	rho	0.28	-	-
	Sig.	*P < 0.000*	-	-
MDADI twelve months	rho	-	0.43	-
	Sig.	-	*P < 0.000*	-
MDADI anchors (-2, -1, 0, +1, +2)	rho	-	-	**0.42**
	Sig.	-	-	***P < 0.000***
Change in MDADI scores from twelve months to baseline	rho	-	-	0.39
	Sig.	-	-	*P < 0.000*

Spearman rho correlation, Sig. (2-tailed)

Mean change

To investigate the MCID, the (+2) anchor point (the group improving by two stages) was excluded to allow the test to perform multiple comparisons, making the total cohort included in the analysis n = 210. Based on the results of the one-way ANOVA, there was a statistically significant difference between the anchor groups *F (3, 206) = 17, p < 0.000*. Results are shown below in Table 39. When looking at the Tukey HSD table (Table 40), all anchor points were statistically significantly different from each other, except for anchors 0 and 1 with the mean difference being +/-5, *p = 0.1*.

The MCID was determined based on the group that showed deterioration by 1 stage (anchor -1) and an improvement of 1 stage (anchor +1), therefore, the MCID for the 100 mL WST is - 4 mL/sec and 5 mL/sec based on the mean change method.

Table 39 Mean change in WST scores from baseline to 12-months based on clinical anchors for n = 210 patients included in the MCID analysis for the 100 mL WST

From baseline to twelve months				
	MDADI anchors	**n (%)**	**Mean ± SD**	**Confidence Interval (95%)**
Change in Swallow Capacity (mLs/sec)	Deterioration of 2 stages (-2)	31 (15)	- 9 ± 8	- 13, - 6
	Deterioration of 1 stage (-1)	68 (32)	- 4 ± 7	- 6, - 2
	No change (0)	98 (47)	- 0.2 ± 8	- 2, 1
	Improvement by 1 stage (+1)	13 (6)	5 ± 7	0.4, 9
	Total	210	- 2 ± 8	- 4, - 1

Table 40 Multiple group comparisons between the anchors using the post-hoc Tukey HSD for n = 210 patients included in the MCID analysis for the 100 mL WST

Clinical anchor (I)	Clinical anchor (J)	Mean difference (I-J)	Standard error	Sig.	Confidence interval (95%)
-2	-1	-6*	2	.004	-10, -1
	0	-9*	2	.000	-13, -5
	1	-14*	2	.000	-21, -8
-1	-2	6*	2	.004	1, 10
	0	-4*	1	.013	-7, -0.5
	1	-9*	2	.001	-14, -3
0	-2	9*	2	.000	5, 13
	-1	4*	1	.013	0.5, 7
	1	-5	2	.126	-11, 1
1	-2	14*	2	.000	8, 21
	-1	9*	2	.001	3, 14
	0	5	2	.126	-1, 111

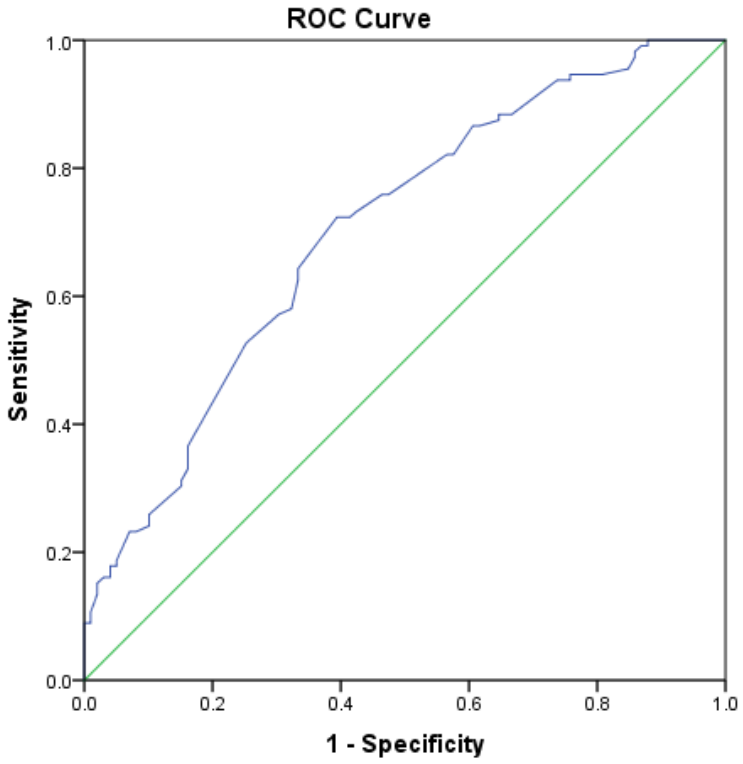
*Results are significant p<0.05

A Kruskal-Wallis H test was also conducted to determine if there were differences in the change in WST in different clinical anchors. Median change in WST scores based on clinical anchors were: anchor -2 (-8 mL/sec), anchor -1 (-4 mL/sec), anchor 0 (-1 mL/sec), anchor 1 (2 mL/sec). The scores were statistically significantly different between clinical anchors $\chi^2(3) = 39.8, p < 0.000$. Subsequently, pairwise comparisons were performed using Dunn's (1964) procedure with a Bonferroni correction for multiple comparisons. The post hoc revealed that there was a statistically significant difference between anchor - 2 (- 8 mL/sec) and anchor - 1 (- 4 mL/sec) (p = 0.017), anchor -2 and anchor 0 (- 1 mL/sec) (p = 0.000), anchor -2 and anchor 1 (2 mL/sec) (p < 0.000), anchor – 1 and 1 (p < 0.001), but not between anchors -1 and 0 (p = 0.061) and anchors 0 and 1 (p – 0.094).

Receiver Operator Characteristics Analysis

The ROC curve for the change in the 100 mL WST shows that the MCID of the 100 mL WST is -4 mL/sec (Figure 25), with a sensitivity of 0.75 (75%) and a 1-specificity 0.46 (46%). The AUC is 0.7 ($p < 0.000$; 95% CI 0.6 – 0.7) indicating an acceptable discriminating range.

Figure 25 The ROC curve for the change in 100 mL WST from baseline to 12-months post-treatment with AUC 0.7 for n = 211 patients included in the MCID analysis for the 100 mL WST



Summary of results

Using two different methods (anchor-based and distribution-based) and three approaches (mean change, ROC curve analysis, and half standard deviation), the MCID for the 100 mL WST is 4 – 5 mL/sec. Suggesting that an improvement of 5 mL/sec or more or a deterioration of 4 mL/sec or more are changes in a clinically relevant way.

6.5 Discussion

This study identified the MCID for the 100 mL WST using the largest available data set for WSTs and MDADIs collected longitudinally. Determining the MCID for outcome measures is important and should be based on multiple methods. It is highly recommended to

triangulate the values yielded from these different methods and then converge to a small range of values or a single value (Revicki et al., 2008). In general, MCIDs are usually calculated for PROs, as PROs have been increasingly reported in clinical trials to compare interventions from patient's perspective and consider patient's concerns and QOL (Copay et al., 2007; Kim et al., 2014; Revicki et al., 2008). Clinician-rated outcomes, however, have longer history in research; hence some studies investigated the MCID for clinician-rated outcomes (Bohannon and Crouch, 2016; Kim et al., 2014; Wise and Brown, 2009). In the current study, the MCID was determined for a clinician-rated outcome measure that quantifies swallowing performance. The 100 mL WST assess speed of swallowing, thus can provide a summary measurement of swallowing function.

In the current study, the MCID was determined using two common methods, the anchor-based method (using two approaches) and the distribution-based method. In the present study, the effect of clinical and demographic factors on the change of the 100 mL WST was investigated, and no such effects were found. Therefore, the estimation was based on the heterogeneous cohort. There is no evidence suggesting that the MCID differs among subgroups (e.g., patients' age, sex, tumour status and treatment groups); still, this should be evaluated (Koorevaar et al., 2018; Revicki et al., 2008). Hence, the MCID can be used for all HNC patients irrespective of the aforementioned factors. The triangulation of values indicate that ≥4 mL/sec is a clinically significant deterioration and ≥5 mL/sec indicate no change, or improvement. Improvements less than 5 mL/sec should not be considered as clinically important, and deterioration of more than 4 mL/sec could indicate a clinically significant deterioration. Previous work have determined a 10 mL change as a cut-off for abnormal swallowing in patients with neurological disorders, however the study utilised a 150 mL of water rather than 100 mL (Nathadwarawala, Nicklin and Wiles, 1992).

There is no consensus on the best method to calculate the MCID, but depending solely on distribution-based methods defeats the concept of meaningful clinical significance from a patient perspective as there methods are purely statistical. Therefore, combining both distribution- and anchor-based methods is recommended (Revicki et al., 2008). In this study, the mean change approach was used to determine the MCID based on a clinical anchor; this approach is commonly used in reporting MCID (Arullendran and Patterson, 2016; Juniper et al., 1994; Koorevaar et al., 2018; Lizaur-Utrilla et al., 2019; London, Stepan

and Calfee, 2014; Maredupaka et al., 2020). Using ROC curve analysis as a method is highly endorsed (Bohannon and Crouch, 2017; Lizaur-Utrilla et al., 2019; London et al., 2014; Maredupaka et al., 2020) and is used in several studies reporting the MCID. The half standard deviation approach was found to be a universally consistent measure for MCID (Norman et al., 2003) and it was originally described by Cohen (1988; 2013) as a medium effect size. The half standard deviation is also a commonly used method in MCID investigations (Arullendran and Patterson, 2016; Bin Abd Razak et al., 2016; Copay et al., 2007; Hutcheson et al., 2015; Kiran et al., 2014; Maredupaka et al., 2020).

Anchor-based methods compare the change in the outcome of interest to an external measure, usually a global question (Rai et al., 2015). Depending merely on a global question of change can be problematic, as the reliability of validity of such questions are unknown, and some patients may have recall bias, in addition to bias influenced by patient's mood and/or recent significant events related to one's life (Crosby et al., 2003; Maredupaka et al., 2020; Revicki, et al., 2008). The MDADI is a PRO that captures dysphagia-specific QOL, and therefore can be used as an instrument to measure changes from patients' perspectives. The MDADI itself is proven to be sensitive to changes over time (Wilson et al., 2011). These properties make it suitable as a clinical anchor, to determine whether changes in a clinical swallowing test (100 mL WST) translates into changes perceived by patients, impacting on their dysphagia-specific QOL. In the present study, the correlation of the MDADI scores and the change in the 100 mL WST, met the recommended guidelines for choosing a clinical anchor (Table 38; Revicki, et al., 2008; Conijn et al., 2014). The relationship between these two measures has been previously reported (Pedersen et al., 2016), confirming that the MDADI is a suitable anchor for determining the MCID for the 100 mL WST. The correlation between these two measures could be attributed to the fact that being able to swallow in a timely is important to the patients.

It has been reported previously that the MCID for the 100 mL WST is 5 – 7 mL/sec (Arullendran and Patterson, 2016). In the present study, the 5 mL/sec change is comparable with that reported previously. However, the MCID for deterioration reported in the current study is 4 mL/sec. This discrepancy could be attributed to several factors. It is unknown which time points contributed to the MCID in the previous study. Moreover, the use of different clinical anchors is known to yield different MCID values, which is in fact one of the

limitations of calculating the MCID (Copay et al., 2007; Rai et al., 2015; Revicki et al., 2008). Furthermore, the previous study had a smaller sample size (n = 121), and the cohort was limited to patients who received (C)RT, with the majority being laryngeal cancer patients. However, the current study found tumour site and treatment type were unrelated to change in the 100 mL WST. It is recommended to use different clinical anchors and then triangulate the results. The PSS-NoD and MDADI are complementary to each other and highly correlated at baseline and twelve months (rho = 0.42 and rho = 0.68, $p < 0.000$; Khan et al., 2015).

The use of ROC analysis shows that a threshold of - 4 mL/sec provides a sensitivity and 1-specificity of 75% and 46%, respectively, with an AUC of 0.7, indicating an acceptable discriminating range. These results were also supported by the mean change method. Determining a - 4 mL/sec change is equated with a meaningful change from the patient's perspective for deterioration. Furthermore, a 5 mL/sec change is equated with an improvement. The MCID for improvement was supported statistically with the distribution-based method which yielded a 5 mL/sec value. It has been suggested that MCID values for deterioration and improvement are not necessarily symmetrical (Revicki, et al., 2008), therefore, a change in direction (increase of 4 mL/sec or a decrease in 5 mL/sec) may not equate to a minimally important improvement and deterioration, respectively. Juniper and colleagues (1994) suggest that the MCID for improvement and deterioration are comparable, supporting the findings of the current study.

6.6 Limitations

This study provides important information regarding the MCID of the 100 mL WST for a large cohort of HNC patients from different treatment centres. However, it is not without its limitations. Regarding the sample size, although there is no consensus on the sample size requirements for determining an MCID, it has been suggested that a sample size of more than n = 100 is sufficient (Lizaur-Utrilla et al., 2019). In the current study, the sample size was n = 211. However, the number of patients in different clinical anchors was relatively small, especially for anchors of improvement (+1 and +2; n = 14). Furthermore, when grouping the patients based on demographics and clinical characteristics, some groups had small sample sizes (e.g., surgically treated patients in comparison with [C]RT patients, and females in comparison with males).

In the current study, the grouping of the MDADI scores was somewhat arbitrary; however, this is common in most MCID studies (Copay et al., 2007). It was hypothesised that moving between MDADI groups (i.e., groups three, two and one) would be significant to the patients. Future research should consider involving clinicians and patients either as a form of Delphi method or as patient and public involvement to finalise the MCID results through discussions and consensus (Rai et al., 2015; Revicki et al., 2008). As this study used secondary data analysis, it was not possible to ask the patients if they would consider the changes as significant or not. Another aspect to consider is the fact that a ceiling effect of 70% was observed at baseline for patients in MDADI group three (scores 80–100), which may explain the high number of patients who demonstrated no change (n = 98, 47%) and the low number of patients demonstrating improvement.

6.7 Clinical Implications

The 100 mL WST provides quantifiable outcomes that enable comparisons over time. Including the 100 mL WST in the Swallowing Outcomes Package can be valuable. It should be acknowledged that the 100 mL is limited in what it can offer. As the test only focuses on thin liquids (water), it does not reflect the patient's capacity to swallow different consistencies. Therefore, the test is not being suggested to replace objective assessments of swallow efficiency and safety, or the CSE; yet, the test offers valuable, useful and gross measures of swallowing performance allowing comparisons. The 100 mL WST is an easy and quick test that can be incorporated into any clinical practice, including Kuwait's. It is well tolerated by patients and sensitive to changes over time. The 100 mL WST is repeatable, does not require a lot of equipment, and somehow resembles the experience of swallowing in daily life. An additional benefit is understanding what is perceived as significant change from the patient's viewpoint. Determining the MCID is valuable for clinical practice. The changes may indicate the need for an intervention such as dilatation for pharyngoesophageal strictures or changes in behavioural swallowing exercises. Moreover, the MCID can guide clinicians in devising individualised goals. In addition, patients can be trained to self-assess and interpret what changes should trigger a need for consultation. All of this adds to the utility of the 100 mL WST in the context of HNC.

6.8 Implications for future research

It is recommended to finalise the MCID value(s) by a method of consensus, or a Delphi-approach. Hence, future investigations should consider expert consensus on the MCID for the 100 mL WST, though the range proposed in the current study is not wide and is reasonable. In the current study, the number of patients who received surgical treatment was small, therefore, future studies investigating the MCID should include larger numbers of patients who were treated surgically and to further investigate if the type of treatment affects the change in the 100 mL WST. Additionally, aspiration status remains a challenging to investigate at the bedside evaluation, future research should also consider calculating the MCID based on aspiration status as a clinical anchor. The use of the MCID for the 100 mL WST as a research outcome could also be explored in longitudinal studies, to compare between statistical and clinical significance. And finally, it would be interesting to calculate the MCID for the 100 mL WST at different time points to explore if the values remain consistent across different time points, or change.

Chapter 7: A prototype of the Three-Step Swallowing Outcomes Package for use in Kuwait

This chapter comprises the prototype of and protocol for implementing the Swallowing Outcomes Package I have described for patients with head and neck cancer (HNC) in Kuwait. The focus is on the recommended outcome measures, selection and timing of administration, there follows a brief discussion on routes to implementation of such a Swallowing Outcomes Package in clinical practice within Kuwait's.

7.1 Summary of the outcome measures

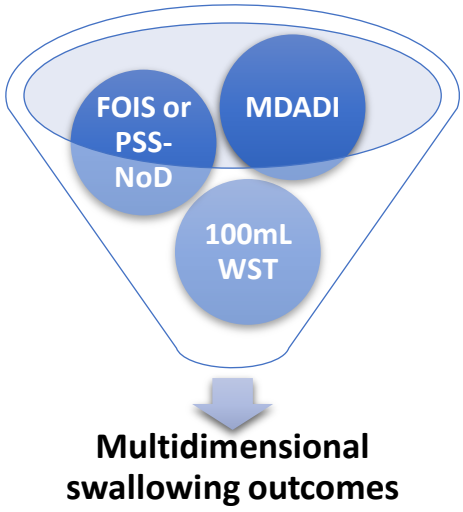
The three different swallowing outcome measures outlined in Chapters 4, 5, and 6 each provide information from a different perspective (see Figure 26).

1- The MD Anderson Dysphagia Inventory (MDADI; Chapter 4), a patient-reported outcome (PRO) measure used to assess the impact of dysphagia on quality of life (QOL). I translated and culturally validated the MDADI for Arabic-speaking individuals in Kuwait following the recommended guidelines. The results demonstrated excellent reliability and validity.

2- Two measures for assessing dietary intake or restrictions were explored from clinicians' perspectives, namely the Functional Oral Intake Scale (FOIS) and the Performance Status Scale - Normalcy of Diet (PSS-NoD; Chapter 5).

3- The 100mL water swallow test (100mL WST) is a measure of swallowing performance. This test has been proven reliable for use for patients with HNC. However, I tested its utility in research and clinical practice by establishing its minimal clinically important difference (MCID; Chapter 6).

Figure 26 Swallowing outcome measures included in the package.



7.2 Why these outcome measures should be used

HNC and its treatment have substantial impacts on patients' swallowing function. Dysphagia seems to be underreported in HNC patients in Kuwait (Chapter 2), and patients also have substantial unmet dysphagia-related needs (Chapter 3). By now, we know that the impact of dysphagia is multidimensional and these dimensions have moderate or no correlation (Baijens et al., 2021); thus, it requires an assessment that uses different outcome measures that report on different paradigms. The more timely the assessments, the earlier and the more productive the opportunity for corrective intervention will be. The use of outcome measures enables clinicians to understand the impact of new treatment methods as they arise through comparing and contrasting the outcomes of each treatment. In addition, it enables them to communicate swallowing profiles to other healthcare professionals, as well as to the patients and their caregivers, using a standard and common language. Finally, outcome measures are crucial for monitoring changes over time, with baseline measures having a predictive value for long-term outcomes.

No consensus exists on the optimal swallowing outcome measures for HNC (Nund et al., 2019). However, outcome measures must have satisfactory psychometric properties and cover different areas of concerns related to dysphagia. The measures selected for this package were required to (1) have valid and reliable results for patients with HNC, (2) provide a distinct paradigm of swallowing outcomes without duplication, (3) offer easy incorporation into any clinical practice, (4) require no or minimal training for the clinicians

and/or patients, (5) be quick and well-tolerated by the patients, (6) be easily collected remotely, and finally (7) be recognised in the HNC dysphagia research literature.

These measures were intended to be combined with a Clinical Swallowing Evaluation (CSE) to serve as a method for monitoring patients' swallowing outcomes throughout the continuum of care. This package, however, does not include a CSE as this was not the focus for this thesis. In Kuwait, each centre/clinician follows a different CSE template depending on their preference. Every CSE must, however, cover the basic components described in Chapter 1. Implementing the swallowing outcome measures suggested in my package can add clinical value as it assesses different paradigms, and it will enable a meaningful comparison of changes over time as well as working towards a standard, systematic collection of data.

Instrumental assessments are sometimes required to determine the safety and efficiency of swallowing, in addition to determine the usefulness of specific swallowing strategies and/or to obtain comprehensive information about swallow physiology (Baijens et al., 2021; Patterson and Wilson, 2011; Speyer et al., 2021). In Kuwait, instrumental assessments are not easily accessed, and furthermore, they are not part of the routine assessment for patients with HNC. Instrumental assessments are usually performed by an otolaryngologist using the Fibreoptic Endoscopic Evaluation for Swallowing (FEES), or by a radiologist using the Videofluroscopic Swallowing Study (VFSS) for Modified Barium Swallow (MBS). This is often accompanied by several difficulties due to the lack of standard procedures, and the speech and language therapist (SLT) may not always be present during the assessment, which could be caused by a lack of awareness of the SLT role during the swallowing exam (e.g., trying out different consistencies and different compensatory strategies). Usually the results are interpreted by the doctor and/or radiologist, and would indicate if the patient is either safe or unsafe to swallow, based on the occurrences of aspiration or penetration. Moreover, there is a limited use of rating scales for instrumental assessments (e.g., DIGEST and PAS) and training in the interpretation of examination results. Patients are referred for instrumental assessment if they show obvious signs of aspiration or penetration during the CSE. However, CSEs are criticised for their lack of sensitivity and specificity in detecting aspiration, therefore, swallowing assessment should depend on different measures. The Swallowing Outcomes Package I propose is expected

to highlight the need of further examination, and/ or contribute to the assessment of the various functional needs of patients with HNC as follows:

1. The MDADI allows clinicians some understanding of patients' perspective on their swallowing difficulty. The MDADI captures the impact of swallowing impairment on everyday living, and provides information on the emotional, social and functional aspects of swallowing. The results of the current study revealed that the A-MDADI was culturally applicable and also well accepted by the Arabic HNC patient population in Kuwait (Chapter 4). The A-MDADI was also demonstrated to be valid and reliable. Furthermore, our research indicated the MDADI could be shortened to five items from the original 20 (Lin et al., 2021). This shortened version of the MDADI may help to reduce burden on patients, improve completion rates, increase the speed of data collection for clinicians, and be more straightforward to score. However, as the shortened MDADI still requires further testing to establish its test–retest reliability, validity and sensitivity to changes over time, the original 20-item version is recommended here.

   The MDADI can flag difficulties that patients perceive in their swallowing, allowing for further discussion between the patient and clinician. Subsequently, rehabilitation may be tailored to address the affected aspects of the patient's life, thus ensuring a more patient-centred management plan as opposed to focusing purely on the impairment.

2. A diet scale, either the FOIS or the PSS-NoD, permits the identification of the level of oral intake or the complexity of diet textures the patients can manage. Both scales have been validated for use by healthcare professionals. This is particularly important as the SLT may not always be present and in constant contact with the patients, and the information provided by either of the scales is beneficial for both SLTs and dieticians. Moreover, clinicians who participated in this study (Chapter 5) agreed that the use of scales would facilitate communication among healthcare professionals, patients, and their caregivers. The use of a diet scale provides information on diet restrictions and allows changes in diet to be recorded systematically throughout and beyond the treatment journey.

3. Finally, the 100mL WST provides a dimension of the impairment that differs from the perspective provided by the MDADI and the FOIS or PSS-NoD. It does this by measuring swallowing performance and efficiency. The 100mL WST provides quantifiable outcomes, requires minimal equipment, and is well-tolerated by patients. The 100 mL WST can also offer some information regarding swallowing safety. Furthermore, establishing its MCID is important, as it increases its clinical utility and allows for a meaningful interpretation of changes over time (Chapter 6). Moreover, the 100mL WST can indicate the need for an intervention such as dilatation for pharyngoesophageal strictures. The 100mL WST can be extended to power future trials, in which it will be a useful measure for interpreting and comparing the swallowing outcomes of different treatment modalities.

7.3 When to assess HNC patients

The advantage of using the three-step Swallowing Outcomes Package is that all these measures are quick, easy, and well-tolerated by patients. The MDADI takes approximately 15 minutes to complete, whereas a clinician takes approximately five to seven minutes to scoring a diet scale. The WST may take seconds or may last up to few minutes (depending on the patient). In total, the administration of the whole package should take approximately 25 to 30 minutes. Collectively, these measures provide quantifiable outcomes, thus permitting comparisons over time, with each outcome measure providing information on a different dimension of swallowing. Research has indicated that all three measures are reliable and sensitive to longitudinal change (Chen et al., 2001; Im et al., 2020; List et al., 1996; Patterson et al., 2014; Patterson et al., 2018).

The timing of swallowing evaluation for patients with HNC is key. Several studies have emphasised the importance of baseline evaluation. In the UK, a pre-treatment swallowing assessment is mandated (Clarke et al., 2016; NICE, 2004). Many patients present with impaired swallowing at baseline (30 to 52%; Platteaux et al., 2010; Kristensen et al., 2020); therefore, pre-treatment swallowing evaluations using appropriate swallowing outcome measures can assist in identifying existing difficulties and allow comparisons with post-treatment outcomes (Patterson and Wilson, 2011; Starmer et al., 2011).

7.3.1 Goals of the baseline evaluation and meeting

a) To provide information to patients and carers about the possible treatment impact on swallowing.

b) To create a benchmark for comparison with post-treatment outcomes. Baseline swallowing outcomes are strongly associated with post-treatment outcomes in the short and long term (e.g., presence of baseline dysphagia; Frowen et al., 2009; Patterson et al., 2011).

c) To identify patients who are at high risk for developing swallowing impairments, based on clinical and demographic characteristics, together with information such as tumour size, site, treatment modalities, patient age, and pre-treatment dysphagia (Figure 27; discussed thoroughly in Chapter 1).

d) To recommend prophylactic swallowing exercises, as evidence suggests early intervention is beneficial for patients scheduled for (C)RT (Carnaby-Mann et al., 2012; Clarke et al., 2016; Loewen et al., 2021; Messing et al., 2017).

Figure 27 Summary of factors associated with the likelihood of developing dysphagia in HNC patients.

Tumour site	Tumour size	Treatment type	Other factors
• Hypopharyngeal tumours	• T3 & T4 tumours	• Mixed modality. • Total radiation dose. • Treatment technique (e.g. open surgeries, conventional RT).	• Older age • Pretreatment dysphagia

7.3.2 Timing schedule

As swallowing fluctuates during and after treatment (Im et al., 2020), it is important to be vigilant and continually evaluate patients during treatment and throughout survivorship, as some patients are at risk for developing late-onset dysphagia (Hutcheson et al., 2013; Kearney and Cavanagh, 2019). This is particularly critical for patients receiving (C)RT

because up to 60% report dysphagia post-treatment (Shune et al., 2012). Frequent evaluations allow for the quick identification of any changes that occur to provide the appropriate intervention. However, the purpose of frequent evaluations goes beyond quick and early identification; regular meetings with patients allow information to be reiterated and continuous education to be provided to improve self-efficiency, ensuring that patients are adhering to prophylactic exercises and dysphagia recommendations, and encouraging oral intake if deemed safe (ENT UK, 2021; Krekeler et al., 2018).

For the timing schedule, I suggest the following time points (providing the associated rationale behind each suggested time). These time points align with the same pathway of care that patients follow with their treating oncologist at the KCCC, hence, patients will not be required to have a different visits to the hospital.

As established earlier, the first point of assessment is at baseline. Following that, surgically treated patients should be assessed post-operatively to with surgeon's clearance in order to compare post-treatment outcomes with baseline and identify any surgically induced swallow performance (Groher and Crary, 2016), it should be noted that collection of MDADI may not be useful for in-patients. Furthermore, surgical patients should be assessed at three-months post-treatment in order to evaluate the effectiveness of recommended swallowing exercises/ strategies, recommend new strategies if warranted, and assess the impact of swallow changes on QOL (Hasegawa et al., 2021).

Regarding patients who receive (C)RT, they should be assessed during treatment, at weeks three, five, and seven (end of treatment), as it has been reported that up to 93% of patients with HNC consume a non-normal diet (Im et al., 2020). Moreover, acute dysphagia symptoms predict late-dysphagia (six months post-treatment; van der Laan et al., 2015). Collecting swallowing outcomes at this time point allows acute dysphagia and changes in swallowing function to be identified and appropriate intervention strategies to be recommended. Since at three-months post (C)RT treatment is the typical nadir of swallowing function (Wilson et al., 2011; Roe et al., 2014), it is important to collect swallowing outcomes at this time-point in order to identify and manage the swallowing difficulties the patients are having. Although swallowing function improves at 12-months post- (C)RT treatment for most patients, it does not return to baseline status. Moreover, up to 28% of patients with HNC aspirate at one year post-treatment (Patterson et al., 2014).

Whereas at two-years post (C)RT, 45% and 7% of patients have dysphagia and aspiration pneumonia, respectively (Hutcheson et al., 2018). Assessing patients and these time points allow early identification of any problems in order to provide appropriate swallowing management that could contribute to improved QOL and reduced morbidity. Table 41 summarises the suggested assessment timing schedule for collecting Swallowing Outcome Measures.

Table 41 Suggested timing schedule for collecting Swallowing Outcome Measures.

Time point	Treatment	Timing
T1	All patients	Baseline
T2	Surgical	Post-surgery with surgeon's permission
	(C)RT	Weeks 3, 5 and 7 during treatment
T3	Surgical	Three months post-surgery
	(C)RT	Three months post-treatment
T4	(C)RT	12 months post-treatment
T5	(C)RT	24 months post-treatment

7.4 Implementation of the package and the next steps

Translating the findings of the current research into clinical practice is crucial. For this to happen, an implementation strategy must be carefully designed to incorporate the package into the healthcare setting at the Kuwait Cancer Control Centre (KCCC). Employing an implementation science model can direct and reduce the gap between research and practice. Implementation models share a multiphase process concerning the exploration for the evidence-based 'intervention', preparation, implementation, evaluation, and sustainability (Aarons, Hurlburt and Horwitz, 2011; NIH, D.A. 2021), and the evaluation of similar constructs, including relative advantage of adopting the new intervention,

intervention characteristics and stakeholders, complexity of change, with a focus on contextual factors in addition to an evaluation of the implementation process itself (Aarons et al., 2011; Damschroder et al., 2009; Rogers, 1962; 2010; Sanson-Fisher, 2004). The design of the implementation strategy is beyond the scope of this PhD and requires future work; however, some of the critical considerations reported above are discussed in the following sections to identify and guide the next steps following this PhD.

7.4.1 Exploration

It is important to identify and engage stakeholders (i.e., healthcare professionals and managers) working with patients with HNC (e.g., oncologists, SLTs, and dieticians) and to maintain this engagement. Throughout the course of this PhD, I have engaged in conversations and discussions regarding HNC dysphagia in general and my Swallowing Outcomes Package with the director of the KCCC, oncologists, nurses, dieticians, and SLTs working with HNC. These discussions, however, have been ad hoc and unfocused. In the next steps, I plan for an active and a targeted dissemination of the Swallowing Outcomes Package. It has been suggested that actively disseminating the evidence base behind any new 'innovation' or research findings through formal and informal channels to key stakeholders facilitates the implementation of that evidence-based innovation (Rapport et al., 2016; Messing et al., 2019). Stakeholders' attention should be directed to the evidence and rationale behind the use of the Swallowing Outcomes Package as a whole, and also to the clinical value each component offers. This may encourage and enhance the adoption and sustainability (long-term implementation) of the Swallowing Outcomes Package instead of continuing the current practice, which does not collect data. It is important to disseminate the evidence base efficiently and effectively (Rapport et al., 2016). Therefore, identifying the channels through which the research findings can be disseminated is key. On an institutional level, dissemination can occur during departmental meetings, or workshops and seminars that take place on regular basis at the KCCC. In addition, one-on-one or small group meetings can effectively facilitate the exchange of information and ideas (Brownson et al., 2018). Using a dissemination planning tool can provide a valuable guide for translating research into clinical practice (Carpenter et al., 2014; Dissemination-Implementation.Org, D.A 2021).

7.4.2 Preparation

It is vital to acknowledge that evidence-based interventions are not universal, and they may require adaptation to fit specific contexts. This adaptation, however, should not affect the fidelity of the interventions. Implementation fidelity refers to the degree of implementing the intervention as it was originally intended (Dusenbury, Brannigan, Falco and Hansen, 2003). Therefore, it is essential to describe the 'core components' of the package (Gearing et al., 2011; NIH, D.A., 2021) to identify how it can be adapted.

The Swallowing Outcomes Package was intended to be locally and culturally appropriate as well as easy to use and incorporate into clinical practice in Kuwait. This was achieved by following a strict adaptation process for the MDADI, and by asking the clinicians about their views and opinions regarding an important component of the package (i.e. the dietary restriction scales), while allowing them to use either scale they were comfortable with. As per the use of the 100mL WST, although it is not particularly specific for the clinical context in Kuwait, its adaptation in different forms is not new to the clinical practice in Kuwait (e.g. different amounts of water trials without timing) and could be considered as a universal measure. The three measures are multidimensional and cover various aspects related to swallowing. Therefore, said measures will comprise the core package, and each of the outcomes will have clear and specific instructions on how to use them and the appropriate training will be provided for the 100 mL WST. The package is intended to be delivered during routine clinical follow-ups via the SLT (for the clinician-rated outcomes: the 100 mL WST and diet scale) and the patient (for the patient-reported outcomes: the MDADI).

Adaptation

It is understandable that it may be necessary to adapt the package to suit the context in which it is being implemented (i.e., KCCC and HNC patient pathway). As the package is intended to be multidimensional, losing one of its components would defeat the package's original purpose. The method of package delivery could, however, be adapted. For example, instead of an SLT collecting the data, the dietician or nurse could collect the data. Additionally, remote delivery (e.g. through tele practice) could be a possibility. Patients with HNC can also be trained to perform the 100 mL WST for self-assessment. Some unpublished data suggest that collecting WST outcomes via video-call is reliable and

feasible. As patients with HNC are the central aim for this Swallowing Outcomes Package use, they should be included in decision-making during and throughout the whole process (Hamilton et al., 2016). It should be acknowledged that generally, it is difficult to determine the adaptable periphery without a period of 'trial and error' (Damschroder et al., 2009). Moreover, it is crucial to acknowledge that implementation with fidelity produces superior outcomes compared with implementation without fidelity (NIH, D.A, 2021). The diet scales and the MDADI does not require specific training, however, for the WST, it requires minimal training and therefore will be provided and appropriately introduced prior to implementation.

Piloting

Piloting the 'core package' may allow an acceptability and understanding of the Package by patients and key stakeholders, as well as identify what the facilitators and barriers are to its implementation; moreover, it should allow for identifying whether adaptation is necessary, and also what should be adapted and how to adapt it. In addition, piloting may permit successful implementation in routine practice (Damschroder et al., 2009). Piloting a new intervention has been perceived as a strong facilitating factor (Damschroder and Lowery, 2013; Messing et al., 2019). A considerable amount of time should be allotted for understanding patients' opinions and perceptions about the new package in terms of its length, value, and rationale. In Chapter 3, I presented preliminary data on the dysphagia needs of patients with HNC in Kuwait; one of the study results indicated that patients had unmet informational needs, especially regarding the trajectory of dysphagia, and also required access to dysphagia services in order to manage the functional and physical impacts of HNC treatment. These results could help in promoting the implementation and routine use of the Swallowing Outcomes Package through informing the key stakeholders about patient needs. The implementation of this package will enable changes in swallowing function to be detected and future outcomes to be predicted.

7.4.3 Implementation and sustainability

Implementation models provide strategies and techniques to improve the adoption, implementation, and sustainability of a new practice by describing essential underlying constructs to move research into practice (Damschroder et al., 2009; NIH, D.A, 2021;

Proctor, Powell and McMillen, 2013). The range of models has been described in implementation science, for example: Diffusion of Innovations Theory (Rogers, 1962; 2010; Sanson-Fisher, 2004), the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009) and the Normalization Process Theory (May et al., 2009). The choice of which model to employ depends on what constructs may influence the intervention implementation in the local setting (e.g. KCCC). Using available online resources can provide a starting point for implementation model selection based on the requirements of the intervention (e.g., www.dissemination-implementation.org) this website for example can provide information on different implementation models and provide training relevant to implementation and dissemination sciences. Continuous evaluation of the implementation process is key to successful implementation and sustainability. The evaluation can take place by collecting qualitative and quantitative feedback about the progress and outcomes of implementation (Damschroder et al., 2009). The obtained feedback can then provide information on the success of efforts dedicated to implementation and the impact of the implemented intervention of the individuals (e.g. survival, QOL for patients with HNC, access to care; NIH, D.A, 2021).

Potential barriers to implementation:

It is important to identify some of the potential barriers to implementation in order to troubleshoot and ensure successful implementation. In this section, I will be briefly describing this. There is some evidence suggesting that lack of awareness and knowledge of new evidence-base practice can be a barrier to implementation (Alatawi et al., 2020). As discussed in section 7.4.1, it is important to engage and spread awareness and education regarding any new evidence base to enhance its adoption. I plan to do so by actively disseminating the evidence behind the Swallowing Outcomes Package, and the importance of having consistent outcome measures in the assessment of HNC dysphagia. Another potential barrier is the lack of resources (Alatawi et al., 2020). All outcome measures in the Swallowing Outcomes Package do not require expensive tools. For example, the 100mL WST does not require special equipment as all items needed are cheap, basic and can be easily accessed in any health setting. The MDADI can be administered electronically, and the FOIS and PSS-NoD are administered by clinicians. Lastly, insufficient support from managers could potentially become a barrier to implementation (Damschroder and

Lowery, 2013). Therefore, engaging key stakeholders from the beginning and gaining their support is essential to ensure sustainability of implementation.

7.5 Summary

In summary, after describing the three-step Swallowing-Outcomes Package comprised of the MDADI, a diet scale and a the 100mL WST, it is important to consider how successfully to implement the package in the clinical practice in Kuwait. Success will require:

- A targeted dissemination strategy of my thesis findings to engage key stakeholders The strategy will require:
    - Setting specific goals and dedicating time and effort.
    - Consideration of stakeholders' and patients' perceptions of the package
    - Understanding of the facilitators of and barriers to implementation
    - A pilot phase to provide an insight on the challenges, different perspectives and potential benefits of implementing the Swallowing Outcomes Package and of what might constitute an adaptable periphery of the Package.

Subsequent plans should also include a carefully selected implementation model that best suits the aims of the Package, and the clinical context in Kuwait to ensure successful implementation and sustainability of the proposed Package. Lastly, continuous evaluation and reflection are invaluable, and therefore should be conducted throughout the whole process.

Chapter 8: Final Discussion and Conclusion

The overall aim of this research was to investigate and identify the gaps related to head and neck cancer (HNC) and dysphagia in Kuwait. The study investigated the prevalence of the disease and symptom in the country, and it assessed the unmet needs of patients experiencing dysphagia as a result of HNC. A key objective was to explore swallowing outcome measures in order to develop a multidimensional swallowing assessment package that is culturally and clinically appropriate for application to patients with HNC in Kuwait.

This study employed different research designs, involving both qualitative and quantitative methods, to achieve the research aim and objectives. The core findings were discussed in earlier chapters; therefore, in this chapter, I provide an overall summary of the thesis, the next steps, limitations and future directions.

To my knowledge, HNC-related dysphagia has not been previously explored in Kuwait. Moreover, the dysphagia services offered to patients in this group are limited due to a lack of trained staff, as the field of speech and language therapy (SLT) is still relatively new. The findings presented in the current study provide a backbone to support the establishment of a robust and high quality SLT service in HNC and the introduction of a core Swallowing Outcomes Package intended for routine clinical practice. In the following sections, I summarise the findings of the empirical chapters of the thesis.

8.1 Summary of findings

The main aim of the thesis was to investigate dysphagia in HNC patients in Kuwait, as this is strongly related to poor quality of life (QOL) and high morbidity. This aim was attained by meeting the following three main objectives:

8.1.1 Investigate the prevalence of HNC and dysphagia in Kuwait

In Chapter 2, I presented the first empirical findings of the thesis. The goal was to scope the scale of the problem by obtaining HNC and dysphagia data, and evaluate their prevalence Kuwait, to justify and facilitate better planning and provision of health and rehabilitative services. The top three prevalent HNC sites based on a convenience sample of 503 patients' diagnoses between 2009 and 2015 were the oral cavity (36%), larynx (23%)

and nasopharynx (19%), with dysphagia being reported by 45% of patients across the continuum of care. The results suggest that dysphagia may be underreported and not fully or systematically investigated. Moreover, the findings of the chapter highlight the necessity of having a proper setting for dysphagia management to appropriately collect data on swallowing throughout the continuum of care.

8.1.2 Understand the experiences and unmet needs of HNC patients in Kuwait

The findings pertaining to this objective were presented in Chapter 3. In this qualitative study, patients described their experiences with dysphagia and their unmet needs. Patients experienced different senses of loss as a consequence of their swallowing difficulties. Moreover, they had to adopt different coping strategies to deal with their eating and drinking difficulties. Patients also had different unmet needs, especially in terms of information and access to various supportive care services. Although previous research has been conducted on the lived experience of dysphagia and unmet needs, but none have been done in Kuwait. Eating and drinking experiences are culturally sensitive, therefore the findings of the study recognised some of these experiences. Furthermore, understanding patients' experiences and needs is an important step to reduce morbidity and improve QOL.

8.1.3 Develop a multi-dimensional swallowing outcomes package to use in Kuwait

In Chapters 4, 5 and 6, I described three swallowing outcome measures that I propose to include in the Swallowing Outcomes Package. These outcome measures were selected as each reflect a different paradigm of swallowing: a Patient-Reported Outcome (PRO) to assess dysphagia-related QOL; the MD Anderson Dysphagia Inventory (MDADI), a clinician-rated outcome that measures dietary restrictions or intake; the Functional Oral Intake Scale (FOIS) or the Performance Status Scale – Normalcy of Diet (PSS-NoD), and a measure of swallowing performance; the 100 mL water swallow test (100 mL WST). Furthermore, these outcomes measures can be easily implemented to the clinical setting as these are inexpensive, does not require a lot of equipment, repeatable, relatively quick, require minimal training, can be collected remotely, and are easily understood by clinicians, patients and the caregivers.

The prototype of the Swallowing Outcomes Package was introduced in Chapter 7 with a proposed timing protocol and some suggestions for dissemination and implementation in clinical practice.

8.1.4 Overall findings

The overall findings of the thesis have aided in forming a preliminary understanding of the gap in dysphagia management for patients with HNC in Kuwait. Moreover, the development of the Swallowing Outcomes Package is expected to fill the void related to the lack of dysphagia identification, highlighting those patients in need of intervention thus limiting the morbidities and lifestyle restrictions associated with dysphagia.

8.2 The importance and contribution of this body of research

This is the first study to report on HNC-related dysphagia in Kuwait in terms of prevalence and patients' needs. The findings are important because they provide the most recent data on the magnitude of the problem in Kuwait. Dysphagia is a major contributor to dehydration, malnutrition and decreased QOL. It also contributes for worse survival (Zebralla et al., 2021).

Moreover, this study developed a Swallowing Outcomes Package consisting of three outcome measures that provide distinct, yet complementary information (Chapters 4–7). In addition, the psychometric properties of the MDADI were further investigated (Lin et al., 2021), and the minimally clinically important difference for the 100 mL WST was determined. While there is a lack of consensus on what outcome measures should be employed for HNC (Nund et al., 2019), the three measures suggested here have satisfactory psychometric properties, in addition to the several advantages discussed throughout the thesis. Furthermore, these measures have been previously reported in literature (e.g., Patterson et al., 2014; Roe et al., 2016). The use of consistent measures across different clinical practices and studies allows for comparison of results and is useful for meta-analyses. Moreover, although the outcome measures suggested here are intended for application in Kuwait, they are suitable for any clinical practice and constitute a useful first, and repeatable step in clinical evaluation.

Each of the outcome measures offers distinct information and complements the others. The MDADI is a PRO and is valuable for assessing the impact of swallowing on QOL, whereas the PSS-NoD or FOIS are important to capture dietary restrictions or method of oral intake. In addition, the 100 mL WST measures swallowing performance; it assesses a patient's capacity to sequentially swallow a 100 mL of water under controlled circumstances (Patterson et al., 2011; Pedersen et al., 2016) and measures the time the patient requires to fully swallow the water and the mean mL per swallow. The 100 mL WST also offers information on measuring swallowing safety (Patterson et al., 2011).

These outcome measures have moderate correlations with one another, suggesting that each outcome provides different information. The MDADI has a moderate correlation both with the PSS-NoD (rho = 0.68) and with the 100 mL WST (rho = 0.45), whereas the PSS-NoD has a correlation of rho = 0.59 with the 100 mL WST (Pedersen et al., 2016). All three measures contribute to creating a good 'swallowing profile' of a patient's swallow, where one domain cannot fully act replace the other.

8.2.1 Important considerations

The findings from this body of work may shed the light on some important considerations when assessing and evaluating the patients. While it is important to understand the biomedical aspect of the illness, an equally important aspect is to consider the patients' narrative and how their values, beliefs and understanding may shape their experiences. It is important to keep an open mind, and allow the patients the opportunity to express their experiences (Koffman et al., 2008). Patients narrative should be with respect to their religious or spiritual beliefs, language, ethnicity, level of education, socio-cultural demographics with a careful consideration of not enforcing stereotypes.

8.3 Next steps

The implications of each study is discussed in the respective chapters. In this section, I summarise and highlight important next steps.

8.3.1 Standardising dysphagia evaluation and management

It is important to appropriately investigate dysphagia via dedicated and appropriate means of evaluation. Moreover, this evaluation should be frequent due to the fluctuation of swallowing in HNC.

In Chapter 7, I suggested the time points for evaluation, using the Swallowing Outcomes Package. In Kuwait, pre-treatment swallowing evaluation is not yet implemented. In fact, the majority of patients are referred for swallowing assessment only once they complain of dysphagia symptoms. This is not in line with the evidence-based recommendations regarding HNC patients' swallowing assessments in other countries (Clarke et al., 2016; ENT UK, 2021; Kraaijenga et al., 2014; NICE, 2004).

Moreover, the Swallowing Outcomes Package will allow to set up a profile of the patient's swallowing, this profile could be easily communicated and understood by other members of the multidisciplinary team (MDT) who are involved in dysphagia care (e.g., dieticians, ENTs). Providing multidisciplinary support to patients with HNC improves outcomes.

Furthermore, it is important to set a plan for the periodic analysis of the outcome measures and discuss the outcomes with the MDT in order to increase accuracy of patient information and improve services.

In addition, patients should be provided with appropriate information about the trajectory of swallowing impairments and the possible treatment-related side effects of swallowing. Such information should be provided not only verbally, to be tailored for each individual patient, but also in written form via booklets or leaflets or information sheets. Patients should be asked for their opinion on the content and language of the information sheets to ensure that these sheets cover patients' information needs. These sheets should be developed by speech and language therapists, in collaboration with other healthcare professionals and the patients themselves, to ensure that information is covered from different perspectives.

8.3.2 Disseminating and implementing Swallowing Outcomes Package

A natural next step to the outcomes of this thesis is the dissemination and implementation of the Swallowing Outcomes Package into clinical practice in Kuwait. In Chapter 7, I

described the next steps for the dissemination and implementation of the evidence-base behind this thesis.

The provisional plan included dissemination of the evidence-base through professional routes on an institutional level (e.g., Kuwait Cancer Control Centre). Scientific meetings, conferences and publications also allow for dissemination of evidence. Another route is the use of social media as these allow a rapid and global exchange and dissemination of information through large platforms (Bhatt et al., 2020; Chan and Leung, 2018). Social media platforms enable all interested members of the public, patients and healthcare professionals to access information (Chan and Leung, 2018; Moorhead et al., 2013). It is also important to consider how other members of the public and patients who do not use such platforms can access information via other means, e.g., posters in waiting areas.

The Swallowing Outcomes Package was not tested for feasibility in the clinical setting in Kuwait. Assessing the feasibility of an intervention has been shown to support successful implementation (Damschroder et al., 2009).

8.4 Education and training

Although education and training of healthcare professionals and patients were not specifically studied in this thesis, both are key for achieving appropriate management for patients with HNC and related dysphagia. Education and training impacts are summarised below.

- Healthcare professionals
    - The acknowledgement of the importance of preventing and early detection of swallowing difficulties associated with HNC, and their associated benefits of reducing morbidity and improving patient's QOL.
    - Training on how to conduct the Swallowing Outcomes Package: Although the MDADI and the diet scales do not require training, the 100 mL WST require minimal training. It is recommended to perform the test on 10 volunteers to ensure reliability and appropriate interpretation (informal communication with the Cardiff Clinical Trials Team).

- Patients
    - Educate patients and empower them by providing them with information about their cancer and related symptoms (e.g., dysphagia) to ensure that they can appropriately engage in conversations about their health, in addition to the skills that enable them to become active members of their own care (WHO, 2009).

8.5 Limitations

The limitation of each study was discussed in respective chapters. However, a limitation of this thesis as a whole is the lack of patient and public involvement. Although this thesis ultimate goal was to improve dysphagia outcomes of patients with HNC, the involvement of patients in the design of the research project and their feedback of the thesis outputs is absent. Patient involvement in research is empowering (Dawson et al., 2020) and offers other advantages such as: increasing the efficiency of research by making it more relevant to the patients, increasing recruitment of research participants, allow researchers to understand how to communicate sensitively with the research participants, how and when to approach potential participants and improving the dissemination of the research outcomes (Greenhalgh et al., 2019; Nuffield Department of Primary Care Health Sciences, 2016).

8.6 Future Directions

Patients should be involved as core members of the dissemination and implementation strategy to continue this research. In addition, as the results of Chapter 3 suggest, patients had unmet information needs, and thus require information materials such as information sheets, infographics and/or educational videos to provide them with the information they necessitate. Patients should also be involved in the co-design of such information booklets, or provide input of the information presented, which may include data generated by the Swallowing Outcomes Package.

Access to instrumental assessment is challenging in the clinical context in Kuwait. As discussed in Chapter 7, there is still lack of use of standard procedures necessary for conducting and interpreting the assessment results. The Swallowing Outcomes Package suggested in the current study will identify patients with dysphagia and therefore may

highlight the need for greater access to instrumental assessments in order to obtain information on the pathophysiology, efficiency and safety of swallowing to inform management and swallowing therapy. Timely access to instrumental assessments remain a long term, fundamental goal. The role of SLT in instrumental assessments should be advocated. In addition, SLTs should get proper training in the conducing and interpretation of instrumental swallowing assessments.

The findings of the current research provided insights on the clinical management of dysphagia in HNC patients in Kuwait. Taken together with evidence from literature, the findings support the initiation of a clinical dysphagia supportive setting in Kuwait to better manage swallowing problems in order to reduce morbidity and improve QOL in patients with HNC. Future work should advocate for the development and sustainability of a clinical pathway for patients from pre-treatment and throughout the continuum of care to collect swallowing outcomes using appropriate, consistent measures and to support early swallowing intervention.

Appendices

Appendix A: Ethical approval for the prevalence of HNC and dysphagia in Kuwait – Newcastle University

04 October 2019

Jenan Altamimi
Institute of Health & Society

Faculty of Medical Sciences
Newcastle University
Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH

FACULTY OF MEDICAL SCIENCES: ETHICS COMMITTEE

Dear Jenan

Title: The incidence and prevalence of head and neck cancer and dysphagia in Kuwait
Application No: 1514_1/5577/2018 (Amendment)
Start date to end date: 24/05/18 to 31/05/20

On behalf of the Faculty of Medical Sciences Ethics Committee, I am writing to confirm that the ethical aspects of your proposal have been considered and your study has been given ethical approval.

The approval is limited to this project: **1514_1/5577/2018 (Amendment)**. If you wish for a further approval to extend this project, please submit a re-application to the FMS Ethics Committee and this will be considered.

During the course of your research project you may find it necessary to revise your protocol. Substantial changes in methodology, or changes that impact on the interface between the researcher and the participants must be considered by the FMS Ethics Committee, prior to implementation.*

At the close of your research project, please report any adverse events that have occurred and the actions that were taken to the FMS Ethics Committee.*

Best wishes,

Yours sincerely

M. Holbrough

Marjorie Holbrough
On behalf of Faculty Ethics Committee

cc.
Professor Daniel Nettle, Chair of FMS Ethics Committee
Mrs Kay Howes, Research Manager

*Please refer to the latest guidance available on the internal Newcastle web-site.

Appendix B: Ethical approval for the qualitative work – experiences and unmet needs of HNC patients in Kuwait – Newcastle University

19 July 2018

Faculty of Medical Sciences
Newcastle University
Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH

Jenan Altamimi PGR
Institute of Health & Society

FACULTY OF MEDICAL SCIENCES: ETHICS COMMITTEE

Dear Jenan,

Title: Service evaluation and unmet needs for HNC patients in Kuwait
Application No: 1517/5666/2018
Start date to end date: 31/05/2018 to 31/07/2020

On behalf of the Faculty of Medical Sciences Ethics Committee, I am writing to confirm that the ethical aspects of your proposal have been considered and your study has been given ethical approval.

The approval is limited to this project: **1517/5666/2018**. If you wish for a further approval to extend this project, please submit a re-application to the FMS Ethics Committee and this will be considered.

During the course of your research project you may find it necessary to revise your protocol. Substantial changes in methodology, or changes that impact on the interface between the researcher and the participants must be considered by the FMS Ethics Committee, prior to implementation.*

At the close of your research project, please report any adverse events that have occurred and the actions that were taken to the FMS Ethics Committee.*

Best wishes,

Yours sincerely

M. Holbrough

Marjorie Holbrough
On behalf of Faculty Ethics Committee

cc.
Professor Daniel Nettle, Chair of FMS Ethics Committee
Mrs Kay Howes, Research Manager

*Please refer to the latest guidance available on the internal Newcastle web-site.

Appendix C: Topic guide for qualitative interview

Unmet needs and service evaluation topic guide - patients

Guide	Questions and probes
General	**1. Can you tell me a bit about your experience with cancer and its treatment?** **2. Tell me what does 'swallowing problems' mean to you?** **3. Tell me about your experience with swallowing problems?**
Service evaluation	**3. Tell me about the services you have used as part of your head and neck cancer care?** **4. Thinking about the care that you are receiving for your swallowing problem is there anything that could be improved?**
Unmet needs	5. **What are your needs that you feel the management team can help you with, in regards of your swallowing difficulty?** **6. What can the management team do that would help you in meeting your needs?**
Conclusion	**7. Do you have anything you would like to add?**

Thank you for your time and for taking part in this research!

Appendix D: Participant information sheet and consent form for the qualitative study (experiences and unmet needs) (English version)

INFORMATION SHEET AND CONSENT FORM

INTRODUCTION & INFORMATION REGARDING THIS BOOKLET

- **Name of principal investigator:** Jenan Altamimi
- **Name of organization:** Newcastle University – United Kingdom
- **Sponsors:** Ministry of Health – Kuwait

This booklet has three sections:

1- Information sheet (to share the project information with you).
2- Certificate of consent for the participant.
3- Certificate of consent for the researcher (you need to sign this to indicate your approval).

PART 1: INFORMATION SHEET

INTRODUCTION

My name is Jenan Altamimi, I am a speech and language therapist from Kuwait. I am doing my PhD at Newcastle University – United Kingdom. I hope to help with eating and drinking problems that are very common with head and neck cancer.

I would like to invite you to take part in my research. Please note that you do not have to take part in this research, and you do not have to decide today. Also, feel free to talk with anyone you feel comfortable with about taking part in this research.

If at any point you feel that you need more clarification, you can ask me about it. If you have any questions or concerns at a later stage, I would still be happy to take the time to discuss the study with you.

PURPOSE OF RESEARCH

Head and neck cancer causes problems in eating, drinking and swallowing foods and drinks. These problems can be the result of the tumour itself, or of the treatment. Eating and drinking problems can cause many complications that impact on your quality of life. Speech and language therapists are healthcare professionals who are qualified in dealing with eating and drinking problems. In Kuwait,

dysphagia services are relatively new, especially for head and neck cancer patients. Therefore, this study aims to discover your unmet needs related to eating and drinking problems during and after your cancer treatment, and to evaluate the services provided to you, in hope that it will help us to improve the quality of care that is provided to you. The interview will focus mainly on your experience with head and neck cancer, its treatment, and your management of swallowing problems.

TYPE OF RESEARCH

This is a qualitative research study. If you agree to participate, you will be interviewed. The interview will mainly talk about your experience with cancer, any swallowing problems, and your needs and opinions of the health care services that you receive. Following that, the whole interview will be transcribed verbatim and translated to English in order to analyse it. Transcripts will be anonymised and any other identifiable information (such as names of places and health professions) will be removed.

PARTICIPANT SELECTION

You are being invited to take part in this research because you have or have had head and neck cancer.

VOLUNTARY PARTICIPATION

Please note that your participation in this research is voluntary. You are not obliged or under any form of pressure to take part in this research. If you participate, you have the complete freedom to withdraw at any point without providing reasons. You may be asked why you want to withdraw from the research, but you do not have to answer. Whether you participate or not, the services you receive in the centre will continue and will remain unaffected.

PROCEDURE

If you decide to take part in this research, you will be interviewed. The interview will be audio-recorded for later analysis.

The interview may be face-to-face or be conducted via a phone interview. The face-to-face interview would be completed only in Kuwait. The phone interview would take place either in Kuwait or in the United Kingdom, where I am currently a student.

All questions are related to your experience and journey with cancer, and the services provided to you. If you feel uncomfortable answering any question, you can say so. If at any time you feel you want to stop, rest, or terminate the interview, you can say so. You can also ask to destroy the interview if you wish.

All personal information that you provide will remain confidential. After completing the data collection period, all names will be destroyed.

It is important to note that the audio-recorded interview, interview transcripts and your information will be taken outside Kuwait to the United Kingdom. These will be stored in separate password protected files. However, they will remain confidential and no one will be able to identify you or your information except me.

DURATION

The interview may take around an hour and a half (90 minutes). However, the duration of the interview may differ slightly between different persons.

RISKS

We did not identify any risks that may be associated with you being interviewed. However, if at any point you become distressed, feel uncomfortable or tired, please let me know so we can address your concerns and/or terminate the session.

BENEFITS

You may feel that there is no direct benefit to you. However, your participation is likely to help us to form a better understanding of the unmet needs of head and neck cancer patients. It will also help us to evaluate the services provided to you, in order to improve their quality. As far as I know, this is the first study to be conducted in this subject in Kuwait. Hopefully, it will provide insight on what are the most common needs that HNC patients in Kuwait share, and ways to meet these needs and enhance the services.

CONFIDENTIALITY

If you take part in this research, all your information will be kept private and will be treated with complete confidentiality. You will be assigned with a code, through which you will only be identified by me and no one else will have access to these information. After the completion of the interview analysis, your name and any other identifiable information will be destroyed.

Your information will be taken to the United Kingdom. All information taken outside or collected outside Kuwait will be kept in password protected files. To protect your anonymity, these files will have the code you were assigned with instead your name.

The whole interview will be transcribed verbatim and translated to English for qualitative analysis. Anything that may identify you will be removed from the interview transcript.

SHARING THE RESULTS

All information you share with us will not be shared with anybody outside the research team, and nothing will be attributed to you by name. The information gathered will be for PhD research, and anonymised results may be disseminated in scientific journals and meetings so that other people who are interested in the topic may learn from the results.

RIGHT TO REFUSE OR WITHDRAW

You do not have to take part in this research. Whether you decide to participate or not, your decision will not affect the services you receive. If at any time you feel that you want to withdraw from the research, you can do so without any concerns. You can also ask for the digital recording to be destroyed.

WHO TO CONTACT

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact me by means of the following:

Email: J.altamimi2@newcastle.ac.uk

PART 2: CERTIFICATE OF CONSENT – PARTICIPANT

Please read the following statements, and initial box where appropriate:

1. I confirm that I have read and understood the foregoing information, or it has been read to me, and that I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without having to provide any reason, and that my decision will not affect the services I receive in the Kuwaiti Cancer Control Centre.

3. **For telephone interviews only:**

I understand that the interviewer is conducting this interview in:

- ☐ Kuwait
- ☐ United Kingdom

4. I am aware that my information, interview recordings and the interview transcriptions will be stored in password protected files in the **United Kingdom** and any identifiable information will be destroyed once the analysis is complete.

5. I understand that the data from the interviews will be fully anonymised and no one will be able to identify me.

6. I agree to take part in this interview and for it be audio-recorded.

7. I wish to be contacted to participate in future studies.

Participant's name:

Date (dd/mm/yyyy):

Signature:

PART 3: CERTIFICATE OF CONSENT – RESEARCHER

Please read the following statements, and initial box where appropriate:

1. I confirm that I have read and understood the foregoing information, or it has been read to me, and that I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without having to provide any reason, and that my decision will not affect the services I receive in the Kuwaiti Cancer Control Centre.

3. **For telephone interviews only:**

I understand that the interviewer is conducting this interview in:

- ☐ Kuwait
- ☐ United Kingdom

4. I am aware that my information, interview recordings and the interview transcriptions will be stored in password protected files in the **United Kingdom** and any identifiable information will be destroyed once the analysis is complete.

5. I understand that the data from the interviews will be fully anonymised and no one will be able to identify me.

6. I agree to take part in this interview and for it be audio-recorded.

7. I wish to be contacted to participate in future studies.

Participant's name:

Date (dd/mm/yyyy):

Signature:

Appendix E: Online consent for qualitative interviews

Participants consent in a phone interview

To obtain participants consent in a phone interview will include the following:

- Confirmation that the individual has read and understood the study information sheet and that they have had the opportunity to ask questions and have had them answered to their satisfaction

- Confirmation that the individual understands that participation in this telephone interview is completely voluntary and a decision not to participate will have no negative consequences on the services they receive at the Kuwait Cancer Control Centre.

- Confirmation that the participant is aware of whether the interview is taking place in Kuwait or in the UK.

- Permission to digitally record the interview. Confirmation that they understand that anything that can personally identify the individual will be removed from the interview transcript and the transcripts will be used for qualitative analysis

- Confirmation that they understand they are free to stop the interview at any point and request digital recording to be destroyed

- Agreement to participate in the telephone interview

After each statement is read the interviewee can say if they agree or understand; the researcher can record this in the box for each statement. The date, time and name of individual and researcher, and agreement to the above will be also be recorded on a consent form

Appendix F: Paper: Psychometric properties of the MDADI – A preliminary study

Dysphagia
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ORIGINAL ARTICLE

Psychometric Properties of the MDADI—A Preliminary Study of Whether Less is Truly More?

Daniel J. Lin[1,2] · Jenan Altamimi[3] · Kim Pearce[3] · Janet A. Wilson[2,4] · Joanne M. Patterson[5]

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Abstract
The MD Anderson Dysphagia Inventory (MDADI) is a 20-item dysphagia-specific QOL questionnaire with four subscales: global, emotional, functional, and physical. It is widely used in clinical practice and in research; however, its psychometric properties have been under-researched. We aim to evaluate the organisation of the MDADI subscales and identify any redundant items. The MDADI is a routinely collected outcome measure at two centres in northeast England. Questionnaires completed at three months following treatment were extracted from these existing databases. Factor analysis was carried out with the aim of reducing redundancy among the set of questionnaire items. Cases with missing values were excluded. A total of 196 complete patient questionnaires were used in factor analysis. A one-factor model accounted for around 50% of the total variance in item responses. The top five endorsed items (abbreviated by the questionnaire item keywords: Excluded, Irritate, Esteem, Social, and Why) in this one factor appeared in three (emotional, functional, and physical) of the four supposed MDADI subscales, i.e. global, emotional, functional, and physical. Our results suggest an overlap of three MDADI subscales across the top five endorsed items. The content of the top five questions all appear related to the psychosocial aspects of swallowing. This implies some redundancy of the items in the original subscales of the questionnaire. Using the most endorsed items, it appears feasible to abbreviate the 20-item MDADI questionnaire to a 5-item "MiniDADI" questionnaire, which is likely to have greater utility in routine clinical practice outside of research settings.

Keywords Dysphagia · Head and neck cancer · Quality of life · Patient-reported outcome · Factor analysis · Deglutition · Deglutition disorders

Introduction

Dysphagia is a very common condition and treatment-related symptom in head and neck cancer (HNC) and is adversely affected by both surgical and non-surgical treatments [1, 2]. It is strongly associated with poorer quality of life (QOL) outcomes, with fundamental changes to eating pattern, social life, and family relationships [2–4]. Dysphagia, thus, remains a significant and serious concern in the long term [5, 6]. Research has consistently shown that swallowing is a top priority concern for HNC survivors [3].

Patient-reported outcomes (PRO) measure patients' health-related QOL (HRQOL) at a single or multiple time points. They are used to collect information about patients' experiences of symptoms, condition and QOL, enabling individual and group level monitoring of outcomes and identification of those in need of intervention. PROs need to have proven reliability and validity to ensure that they are fit for clinical purpose. A practical and effective PRO should

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measure the underlying constructs of the questionnaire with minimal response fatigue [7].

The MD Anderson dysphagia inventory (MDADI) is a self-administered dysphagia-specific QOL questionnaire [8], designed to capture patient perceived problems for those treated for HNC. The MDADI is the first valid and reliable tool that is concerned with dysphagia-specific QOL for HNC patients, making it one of the most widely used QOL questionnaires clinically and in research settings [9, 10]. The MDADI was used as a primary or a secondary endpoint in clinical trials, e.g. PATHOS, DARS and ORATOR [11–13], also in validating new scales [14] and in determining the feasibility and utility of interventions (for example, investigating the effectiveness of pre-treatment swallowing exercises on post-treatment swallowing QOL [15]), efficacy of acupuncture on swallowing-related QOL [16], the feasibility of cognitive-behavioural swallowing therapy [17], and the effectiveness of electrical stimulation on swallowing [18]. It was also used to report on swallowing function in longitudinal studies [5, 19, 20].

Having a tool that is both clinically relevant to patients and has good psychometric properties is essential. Initial MDADI concepts were, however, developed through focus groups of head and neck surgeons and speech pathologists from a single centre, few with personal experience of dysphagia. The phrasing of the questionnaire was subsequently refined in focus groups of HNC patients with dysphagia. The final questionnaire consists of 20 items (listed in Appendix A) and includes four subscales: global (one item), emotional (six items), functional (five items), and physical (eight items) [8]. The global assessment is scored individually, while the other items in each subscale are summed and the mean score is multiplied by 20 to obtain a score that ranges from 20 (extremely low functioning) to 100 (high functioning). The MDADI has good internal consistency reliability (Cronbach alpha coefficient = 0.96) and a test–retest reliability correlation ranging from 0.69 to 0.88 for all of its subscales. The MDADI also proved to be valid in terms of criterion and construct validity when compared against the Performance Status Scale (PSS) dysphagia measure and the Short Form Health Survey (SF-36) HRQOL tool, respectively [8].

To date, the psychometric properties of the MDADI including its construct validity have been under-researched. In the initial development of the scale, although the authors investigated the questionnaire's reliability, content, criterion, and construct validity, further analysis to identify any item redundancy was not undertaken. The current MDADI questionnaire in its full length covers two full pages; it can be difficult to score for the non-expert and can be potentially cumbersome for patients to complete, thereby potentially reducing the accuracy of answers [21] especially when administered repeatedly on follow-ups and, particularly, when combined with other clinical assessments [7]. Patients are also now frequently asked to complete other PROs such as HRQOL questionnaires, where there might be a degree of overlap in the clinical scales being measured. Furthermore, some centres may be collecting these data remotely via telehealth, which can be time consuming for both the assessor and patient if applying the MDADI. Therefore, we aim to evaluate the underlying psychometric construct of the MDADI and identify any redundant items.

Patients and Methods

Databases

Three databases collated at two university teaching hospitals in northeast England were used for this analysis. These databases were set up for audit or research purposes and included the MDADI as part of a battery of swallowing outcome measures. Patients were consecutively and prospectively approached, and their data were anonymised when enrolled into the databases. The focus of the databases was 1) a service evaluation of functional outcomes for minimally invasive surgery (transoral laser microscopy (TLM) or transoral robotic surgery (TORS)), 2) a research database recording swallowing outcomes for non-surgical primary treatment (chemotherapy (CRT) or radiotherapy (RT)), and 3) a feeding tube audit comparing outcomes for those receiving a reactive nasogastric tube (NGT) or prophylactic radiologically inserted gastrostomy (RIG) tube for primary or adjuvant (chemo)radiotherapy.

Questionnaire

The MDADI was routinely collected pre-treatment, three, and 12 months post-HNC treatment. Questionnaires completed at three months were extracted from these existing databases. This time point was chosen as it represented the greatest deterioration in post-treatment MDADI scores and contained a full range of the scale of responses. It therefore maximised coverage of most questionnaire items [3, 20]. In order to conduct factor analysis on the patient responses, a wide range of scores is desirable [22, 23]. We opted not to use data from the same patient twice (e.g. both three and 12-month time points), as their questionnaire interpretation and responses would be very similar. Each of the 20 MDADI items are rated on a 5-point Likert scale ranging from 1: "strongly agree" to 5: "strongly disagree", except for questions abbreviated by "Conscious" and "Eat Out" (Appendix A) whose ratings are scored in reverse order ranging from 5: "strongly agree" to 1: "strongly disagree". A composite MDADI score was generated by calculating the mean response for the 19 items (excluding the global question) making up the emotional, functional and physical subscales

and multiplying the result by 20, resulting in a score ranging from 20 representing a low QOL function to 100 indicating high QOL function[8]. All MDADI question responses were inputted into the data extraction sheet for analysis.

Factor Analysis

The data were analysed using IBM SPSS Statistics for Windows, version 24 (IBM Corp., Armonk, N.Y., USA). Multivariate factor analysis was carried out to examine relationships between multiple ordinal questionnaire items each measured on a Likert scale and collected from the 3-month MDADI questionnaire. By exploring the structure of the data in this manner, we were informed as to whether item reduction was viable.

It is recommended that at least ten completed questionnaires per questionnaire item are used for factor analysis implementation [22, 24, 25].

For this study, factor analysis was carried out using the most recommended and utilised combinations of options [24], i.e. (i) principal axis factoring (PAF) and (ii) principal components extraction. Principal axis factoring is, strictly, a "factor analysis" method whereas factor analysis with principal components extraction is often termed "PCA". Although different in their mathematical derivation, factor analysis and PCA share a common aim: to identify the underlying dimensions in the data. It is, however, acknowledged that there is no guarantee that factor analysis and PCA will result in the same solution [23, 26]. Formally, the dimensions are called "factors" (in factor analysis) and "components" (in PCA); however, for readability, we have termed both entities "factors".

In a factor analysis, the total number of factors equals the number of items in the questionnaire. Each factor captures a proportion of the overall variance in the observed items. Factors are output in the order of how much variation they explain with the eigenvalue representing the variance explained by a particular factor. The first factor is, thus, the most important and accounts for the largest amount of variance in the data. Factors that explain the least amount of variance are discarded. In this study, factors with eigenvalues greater than 1 were retained [27].

To allow for better differentiation of the factors, factor rotation was utilised. Orthogonal rotation results in independent factors; oblique rotation allows the factors to correlate. As there was no consensus as to whether or not the underlying factors should be related, both direct oblimin (oblique) and varimax (orthogonal) rotation were employed.

For interpretation purposes, the weights (loadings) of the items for each factor are considered, i.e. items having a large weight are used to label a factor. In a factor analysis, these loadings describe the strength of the relationship between each MDADI question and the underlying factor. Factor loadings were initially interpreted with an absolute value greater than 0.5 [28]. Recognising that a factor loading threshold greater than 0.5 is acceptable whilst one that is greater than 0.7 is deemed good [29], a more stringent factor loading threshold of greater than 0.7 was used to identify the top endorsed MDADI items.

The Kaiser–Meyer–Olkin measure of sampling adequacy and Bartlett's test were generated to ensure that the criteria for a satisfactory factor analysis were met [24].

As highlighted by a recent systematic review by Patel et al. [30], the MDADI did not include a plan for missing data. Missingness in this study was assessed by evaluation of the percentage of questionnaire responses missing for each item. Participant anonymisation at previous enrolment to the databases precluded a statistical assessment of differences in demographic and clinical characteristics between those who submitted complete and incomplete MDADI questionnaires.

The top five endorsed items using PAF and PCA were checked for agreement and descriptive statistics for each item were generated. Cronbach's alpha was used to evaluate the psychometric properties, reliability, and internal consistency of the MDADI, with an acceptable value ranging from 0.7 and 0.9, where higher values would suggest redundancy of items [31]. Preliminary validity assessment was also carried out with a view to future expansion.

Results

Patient Characteristics

There was a total of 239 patients identified from the three databases. Of the 216 patients with complete treatment data, there were 30 patients in database one (the minimally invasive surgical (TLM/TORS) group), 142 patients in database two (the non-surgical (CRT/RT) group), and 44 patients in database three (the feeding tube group (NGT/RIG)). Patient demographics for the entire cohort are summarised in Table 1.

MDADI Responses

Of the total MDADI responses, 20 questionnaires had missing values. No more than 5% of questionnaire responses were missing per item (Table 2). After removing the 20 missing questionnaires, 196 questionnaires were available for the factor analysis. The 3-month composite MDADI scores ranged from 22.1 to 100, and the mean composite score was 68.6. The internal consistency of the MDADI questionnaire responses was assessed using the Cronbach's alpha statistic. Cronbach's alpha was 0.939 for all questions combined, excluding the global item question: "My swallowing ability limits my day-to-day activities".

Table 1 Patient demographics

Parameter	Patients (*n*)	Percent (%)
Total	239	100
Gender		
Male	191	79.9
Female	48	20.1
Site		
Oropharyngeal	93	38.9
Hypopharyngeal	32	13.4
Laryngeal	82	34.3
Nasopharyngeal	10	4.2
Unspecified	22	9.2
T stage		
T1	49	21.1
T2	46	19.8
T3	52	22.4
T4	63	27.2
Tx	22	9.5
N stage		
N0	88	40
N1	52	23.6
N2	73	33.2
N3	7	3.2
Age		
Minimum	41	
Maximum	89	
Mean	63.3	

Initial Selection of Factors

Factors were initially selected having eigenvalues greater than 1. Three factors met this criterion (Fig. 1). The percentage of variance in item responses accounted for by the first, most important, factor was around 50% (before rotation). Items having large loadings within these three factors (after rotation) were further examined.

Principal Axis Factoring (PAF)

Principal axis factoring (PAF) was performed with oblique rotation and the loading for each item was observed within the three retained factors (Fig. 2). We then identified loadings over the 0.5 threshold (in absolute value). The top loading items occurred within the first two factors (Fig. 3).

Top Endorsed MDADI Items

When a more stringent loading threshold of 0.7 is taken, the five top MDADI items in the first, most important, factor were identified, and these are summarised in Table 3. When compared to their original subscales, two of the items are functional, two are emotional, and one is related to a physical subscale.

Principal Components Analysis (PCA)

Factor analysis with principal components extraction was then performed with oblique and orthogonal rotation and compared to PAF with oblique and orthogonal rotation (Table 4). Based on factor loadings and a threshold of 0.7, the top five items in factor 1 for PCA were consistent with those of PAF, regardless of method of rotation.

Internal Consistency and Tests of Validity

The questionnaire responses from the top 5 items from factor 1 were assessed and found to have a Cronbach's alpha of 0.9. Additionally, there was a significant difference when comparing the MDADI responses for the surgical (TLM/TORS) versus non-surgical (CRT/RT) groups averaged across the top five items in factor 1 ($p=0.0004$, unpaired t-test). This differentiation between known groups is an indicator of construct validity [22]. Furthermore, association was established between (i) the mean score of the aforementioned two items from the functional subscale, (ii) the mean score of the aforementioned two items from the emotional subscale, and (iii) the score from the one item from the physical subscale and the functional, emotional, and physical subscale scores, respectively, of the original MDADI (Pearson's correlation coefficient for factor 1 subscale mean scores versus corresponding original MDADI subscale scores: emotional, $r=0.85$; functional, $r=0.93$; and physical, $r=0.64$), thus, providing evidence that a reduced instrument would be valid.

Discussion

This study aimed to identify the most important underlying MDADI questionnaire construct using retrospective data from HNC patients and explored the potential to abbreviate the MDADI for clinical and research purposes. Our study evaluated 196 MDADI questionnaires from surgical and non-surgical HNC patients. We attempted to cover all HNC sites, stages, and treatment modalities, by including consecutive HNC patients with a spectrum of disease and treatment-related dysphagia severity.

By performing exploratory factor analysis on this cohort of MDADI responses, we found a single underlying questionnaire construct (factor) which remained consistent across all methods of statistical enquiry using principal components analysis and principal axis factoring. Throughout our statistical interrogation, the same 5 questions (loading onto the single factor) were repeatedly identified. The 5 questions (and their corresponding subscales) were

Table 2 Missing values analysis

Univariate statistics							
	N	Mean	Std Deviation	Missing		No. of extremes[a]	
				Count	Percent	Low	High
Activity	215	3.15	1.342	1	.5	0	0
Embarrassed	214	3.60	1.145	2	.9	14	0
Cooking	214	3.43	1.315	2	.9	0	0
End of Day	212	3.42	1.180	4	1.9	0	0
Conscious	213	3.08	1.241	3	1.4	0	0
Upset	215	3.12	1.351	1	.5	0	0
Effort	215	3.04	1.356	1	.5	0	0
Go Out	216	3.83	1.118	0	.0	32	0
Income	212	3.86	.135	4	1.9	27	0
Longer	211	2.52	1.292	5	2.3	0	0
Why	213	3.44	1.154	3	1.4	0	0
Irritate	214	3.81	.952	2	.9		
Cough	213	3.30	1.278	3	1.4	0	0
Social	213	3.35	1.307	3	1.4	0	0
Eat Out	214	3.07	1.311	2	.9	0	
Limit	214	3.05	1.328	2	.9	0	0
Weight	214	3.35	1.192	2	.9	0	0
Esteem	214	3.60	1.158	2	.9	19	0
Amount	210	3.53	1.107	6	2.8	10	0
Excluded	213	3.67	1.156	3	1.4	17	0

[a]Number of cases outside the range (Q1−1.5*IQR, Q3 + 1.5*IQR)

Q1 = first quartile, Q3 = third quartile, IQR = interquartile range

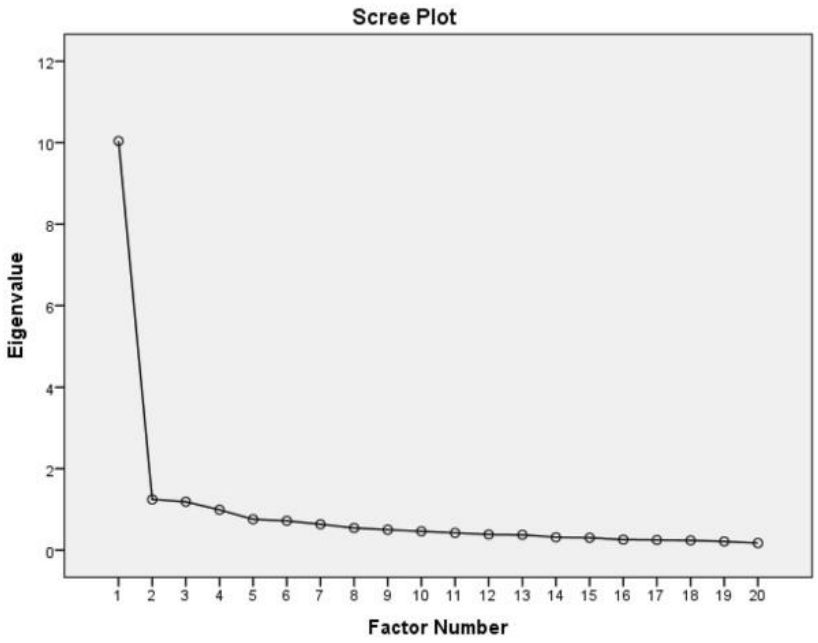

Fig. 1 Scree plot of MDADI factors. MDADI factors shown along X-axis and corresponding eigenvalues along y-axis. Factors 1–3 had eigenvalues greater than 1

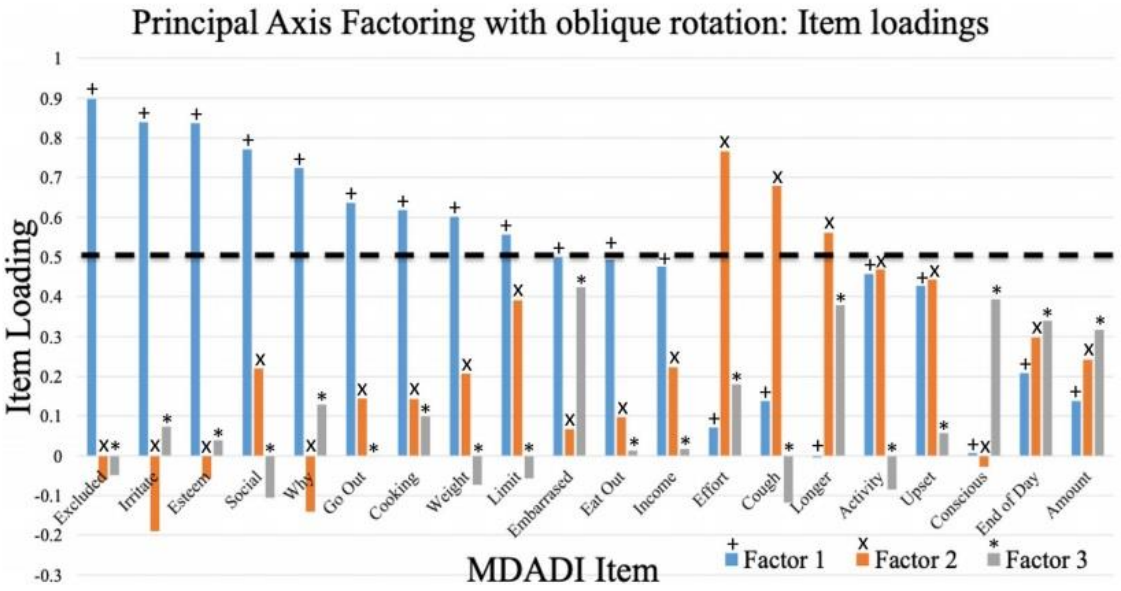

Fig. 2 Examination of factor loadings greater than a 0.5 threshold

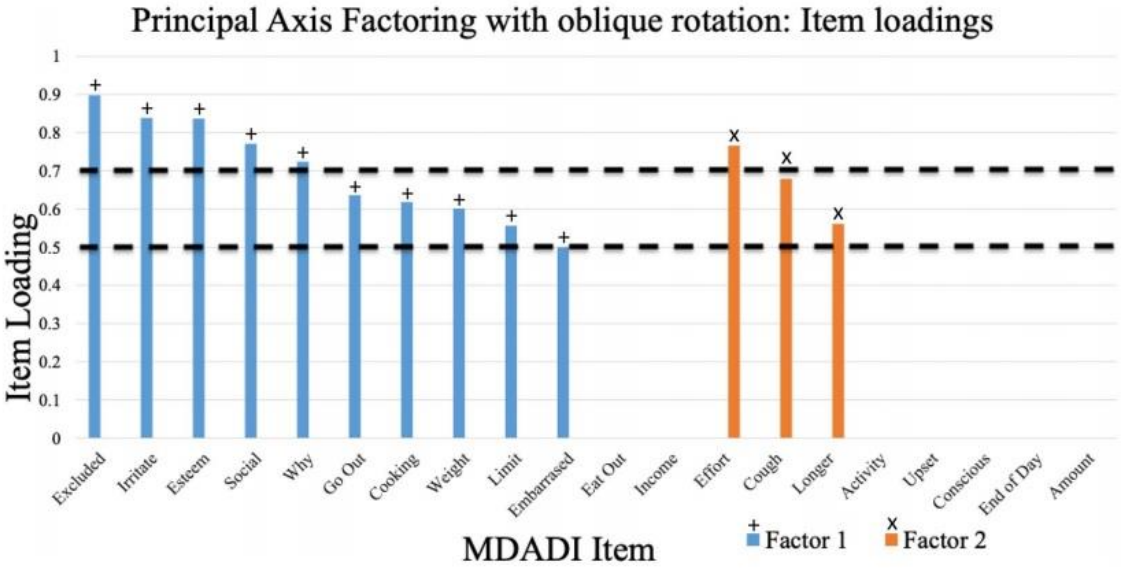

Fig. 3 Identification of a factor with stringent item loadings greater than a 0.7 threshold

(1) I feel excluded because of my eating habits (Functional)
(2) Other people are irritated by my eating problem (Emotional)
(3) I have low self-esteem because of my swallowing problem (Emotional)
(4) My swallowing problems limit my social and personal life (Functional)
(5) People ask me, "Why can't you eat that?" (Physical)

Table 3 Top 5 MDADI items from factor 1 ranked in order of loading and matched to the original MDADI subscales

Factor 1 Loading (Rank)	MDADI Question	Subscale
0.898 (1)	I feel excluded because of my eating habits	Functional
0.839 (2)	Other people are irritated by my eating problem	Emotional
0.837 (3)	I have low self-esteem because of my swallowing problem	Emotional
0.771 (4)	My swallowing problems limit my social and personal life	Functional
0.724 (5)	People ask me, "why can't you eat that?"	Physical

Table 4 Comparison of MDADI factor 1 loadings for PAF and PCA

Extraction Method		PAF		PCA	
Rotation Method		Oblique	Orthogonal	Oblique	Orthogonal
MDADI Item	Abbreviation	Factor 1 Loadings			
I feel excluded because of my eating habits	Excluded F4	0.898	0.768	0.864	0.796
Other people are irritated by my eating problem	Irritate E3	0.839	0.709	0.912	0.794
I have low self-esteem because of my swallowing problem	Esteem E6	0.837	0.731	0.836	0.775
My swallowing problems limit my social and personal life	Social F3	0.771	0.710	0.705	0.722
People ask me, "why can't you eat that?"	Why P3	0.724	0.627	0.845	0.739

These 5 questions appeared in the 3 different subscales of the original MDADI (emotional, functional, and physical), suggesting that they may all be related to the same underlying questionnaire construct.

Our results reveal that at three months post-treatment, when patients show the most deterioration of swallowing function, the most highly endorsed items are related to functional and emotional aspects rather than the physical aspects, in spite of the physical subscale having the most items, eight, compared with five and six for the functional and emotional subscales, respectively. This substantiates the MDADI questionnaire as a dysphagia-specific QOL scale rather than a patient reported symptom scale. Moreover, even the retained item in the physical subscale is related to a social context more than a physical impairment of swallowing (P3: People ask me: "Why can't you eat that?"). The psychosocial impact of dysphagia is well documented in the literature, characterised by avoidance of social eating, anxiety over mealtimes, isolation and low self-esteem [32–35]. Items covered in this reduced MDADI represent these commonly reported problems, and we suggest referring to this abbreviated version as the "MiniDADI".

In the original MDADI paper [8], the Cronbach alpha for the total MDADI score was 0.96, suggesting some redundancy of items within the questionnaire. The internal consistency for the top five endorsed items was 0.9 after factor analysis was applied in our study and was, therefore, deemed to be within the acceptable value range for the Cronbach's alpha statistic. Thus, shortening the MDADI to 5 questions from 20 questions did not jeopardise its reliability in terms of internal consistency. Interestingly, the top 5 questions identified did not include the global question: "My swallowing ability limits my day-to-day activities" (abbreviated as "Limit", Appendix A). A plausible explanation for this is that a large proportion of the variance in questionnaire responses could be accounted for by the top 5 questions in factor 1. The global question, although widely used in current practice as a quick measure of dysphagia, did not account for enough of the response variance to be used as a standalone discerning item from the MDADI questionnaires which were tested in this study.

Construction of the MiniDADI scores would follow the same procedure as that of the standard MDADI, i.e. multiplying the mean of the responses from the 5 included questions by 20, generating a score ranging from 20 representing a low QOL function to 100 indicating high QOL function.

Limitations

This study has several limitations that should be noted. This retrospective analysis was limited in geographical generalisability as it only included patients who were treated at

two centres in the northeast of England. The assessment of missingness, and hence potential bias in analysis, could only be performed by confirming that there was less than 5% of questionnaire responses missing per item. Because participant responses had already been anonymised at the time of enrolment to the databases, it was not possible to retrospectively analyse for any difference in the demographic and clinical characteristics between complete and incomplete questionnaire responders. Thus, it was only possible to partially confirm that incompleteness occurred at random due to the small proportion (< 5%) responses missing per item [36]. It should also be borne in mind that the analysis performed in this study was an exploratory factor analysis which identified and statistically justified a single underlying questionnaire construct (factor 1).

The MDADI questions abbreviated by "Effort" and "Cough" appear to have large loadings, but as seen on Figs. 2 and 3, and these items are predominant on factor 2. Thus, they represent a different (and less statistically important) "dimension" in the data. As already demonstrated, factor 1 is primarily associated with the social aspects of dysphagia whereas "Effort" and "Cough" are concerned with the physical and have not been included in the MiniDADI. In the future, however, the MiniDADI may be expanded and explored using two subscales – the first containing the aforementioned 5 items and the second having 2 items from the original MDADI physical domain.

It is recognised that Cronbach's alpha is the only measure of reliability that has been conducted on the MiniDADI so far. Test–retest reliability will be carried out in the future. Differentiation by known groups is an indicator of construct validity [22], and in this study, it was indeed established that the mean 3-month MiniDADI scores for TLM/TORS (83.3) was significantly higher than CRT/RT (70.3) ($p = 0.0004$). Assessment of concurrent criterion validity and construct validity (both convergent and divergent) involves the correlation of MiniDADI scores with other measurements which are taken simultaneously. The MiniDADI is composed of items from the functional (2 items), emotional (2 items), and physical (1 item) MDADI subscales; upon investigation of the correlation between the associated three MiniDADI *subscale* scores and the corresponding three subscales of the original MDADI, strong correlation was found (Pearson's correlation coefficient for MiniDADI subscale mean scores versus corresponding original MDADI subscale scores: emotional, $r = 0.85$; functional, $r = 0.93$; and physical, $r = 0.64$), thus, providing evidence that an abbreviated instrument is valid. In the future, evaluation of concurrent validity will be carried out using a separate cohort of HNC patients by looking at associations between the MiniDADI and a gold standard (e.g. Eating Assessment Tool (EAT-10) or Swallowing Quality of Life questionnaire (SWAL-QOL)); relationships between the MiniDADI and a related construct (e.g. Sydney Swallow Questionnaire) will be examined to assess construct validity. Further testing would also ensure that the MiniDADI score is sufficiently robust to be used in the assessment of minimal clinically important difference (MCID) [37]. The authors' advise against clinical use of the MiniDADI until further validation is completed.

Conclusion

Factor analysis performed on this group of patients has generated a model for the MDADI questionnaire which appears to be explained by a single underlying factor. The single factor isolated incorporates an overlap of 3 of the original MDADI subscales and implies some redundancy of questions in the MDADI. In the increasingly busy clinical HNC setting, it appears that the single underlying construct of the MDADI can be tested in a quick and robust manner by using the 5 top loading question items identified in factor 1.

PROs are an essential component of treatment and disease-related outcome assessment and should be collected at regular intervals, before and after treatment. Reliable, valid, and acceptable tools are required to reduce patient burden, increase response rate, and produce robust data to encourage more longitudinal assessments of dysphagia in HNC. This initial study identified that an abbreviated MiniDADI may be a suitable PRO, with further testing required to substantiate these findings before implementation in routine clinical practice.

Appendix A

The M. D. Anderson Dysphagia Inventory (MDADI) with corresponding abbreviations and subscale.

Subscale MDADI question	(Abbreviation)
(G) My swallowing ability limits my day-to-day activities.	(Limit).
(E) I am embarrassed by my eating habits.	(Embarrassed).
(F) People have difficulty cooking for me.	(Cooking).
(P) Swallowing is more difficult at the end of the day.	(End of Day).
(E) I do not feel self-conscious when I eat.	(Conscious).
(E) I am upset by my swallowing problem.	(Upset).
(P) Swallowing takes great effort.	(Effort).
(E) I do not go out because of my swallowing problem.	(Go Out).

Subscale MDADI question	(Abbreviation)
(F) My swallowing difficulty has caused me to lose income.	(Income).
(P) It takes me longer to eat because of my swallowing problem.	(Longer).
(P) People ask me, "Why can't you eat that?"	(Why).
(E) Other people are irritated by my eating problem.	(Irritate).
(P) I cough when I try to drink liquids.	(Cough).
(F) My swallowing problems limit my social and personal life.	(Social).
(F) I feel free to go out to eat with my friends, neighbors, and relatives.	(Eat Out).
(P) I limit my food intake because of my swallowing difficulty.	(Limit).
(P) I cannot maintain my weight because of my swallowing problem.	(Weight).
(E) I have low self-esteem because of my swallowing problem.	(Esteem).
(P) I feel that I am swallowing a huge amount of food.	(Amount).
(F) I feel excluded because of my eating habits.	(Excluded).

Declarations

Conflict of interest None declared.

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Appendix G: Ethical approval for the MDADI study – Newcastle University

Newcastle University

Faculty of Medical Sciences
Newcastle University
The Medical School
Framlington Place
Newcastle upon Tyne
NE2 4HH United Kingdom

Jenan Altamimi
Institute of Health & Society

FACULTY OF MEDICAL SCIENCES: ETHICS COMMITTEE

Dear Jenan,

Title: Head and neck cancer in Kuwait: developing dysphagia services
Application No: 1441_1/2025/2018
Start date to end date: 24/12/2017 to 20/12/2018

On behalf of the Faculty of Medical Sciences Ethics Committee, I am writing to confirm that the ethical aspects of your proposal have been considered and your study has been given ethical approval.

The approval is limited to this project: **1441_1/2025/2018**. If you wish for a further approval to extend this project, please submit a re-application to the FMS Ethics Committee and this will be considered.

During the course of your research project you may find it necessary to revise your protocol. Substantial changes in methodology, or changes that impact on the interface between the researcher and the participants must be considered by the FMS Ethics Committee, prior to implementation.*

At the close of your research project, please report any adverse events that have occurred and the actions that were taken to the FMS Ethics Committee.*

Best wishes,

Yours sincerely

Kimberley Sutherland
On behalf of Faculty Ethics Committee

cc.
Professor Daniel Nettle, Chair of FMS Ethics Committee
Mrs Kay Howes, Research Manager

*Please refer to the latest guidance available on the internal Newcastle web-site.

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Appendix H: MDADI translation reports

Initial translations

Informed translator, T1 – Nour Al-Rshaidan

تحد النشاطات اليومية هي عبارة غير مفهومة بشكل مباشر، لذلك كان من الضروري أن أضيف كلمة "ممارستي."

وفي اللغة العربية لا نستخدم ترجمة - day to day يوم ليوم بل نقول اليومية و هي تكفي لتوضيح المعنى

E2 أوضح في المعنى خصوصا أن محرج تحتاج تشكيل و انتباه لقراءتها بالطريقة الصحيحة فقد يكون معناها أنني مُحرج للآخرين.

P2 يجب إضافة الطعام و لشراب لتوضيح المعنى ، كلمة بلع لا تستخدم وحدها في هذا السياق

P2 نهاية اليوم أشك بأنها تكون واضحة للمريض مثل الليل.

E7 من الصعب ترجمة self-conscious بأنها وعي و انتباه الانسان لنفسه، و حيث انها تتضمن الاحراج و التوتر قد نقوم بإضافة ذلك لتوضيح المعنى.

E4 كلا العبارتين صحيح

P6 في هذا السياق أظن انه من الواجب اضافه الطعام و الشراب

F5 خسارة مصدر الدخل اصح و لكنها غريبة للقارئ

F3 تحدمن حياتي الاجتماعي أجد أن معناها ضعيف و غير واضح مثل قدرتي على ممارسة للحياة الاجتماعية

F5 هنا قد تعني الترجمة أن المريض يتناول كمية محدودة بأمر الطبيب و ليس باختياره

E6 في اللغة العربية نستخدم تقدير الذات و لكن الدارج اكثر و الاقرب للفهم هو الثقة بالنفس

إضافة الطعام والشراب افضل لسياق الجملة و لكن ليست اساسية

P4 أضفت اثناء تناول الطعام لتوضح أن البلع هو ليس كمية الوجبة ذاتها بل هو كمية اللقمة لأننا نستخدم كلمة البلع باللهجة الكويتية عن الاكل عند السخرية /الضحك

Translation

- I added the term ‘pursuing’ before the phrase ‘Daily activities’ when translating the first question to make it more accurate in Arabic language.
- I recommend using ‘eating, drinking and swallowing’ instead of just swallowing to make it more obvious.
- P2: it is better to use ‘at night’ instead of ‘end of the day’.
- E7: The term ‘self-conscious’ is not easily translated into Arabic, and if it was literally translated it would be complicated and won’t convey the desired meaning. Therefore, I adapted it to the terms ‘stressed and embarrassment’.
- P6: I think it is better to add the terms ‘eating and drinking’ instead of just swallowing.
- F5: the term ‘job’ would make more sense than ‘income’ in Arabic population.
- P5: This is ambiguous, as it may mean that eating less food is because of following the doctor’s orders.

- E6: Self-esteem is better translated into self-confidence as it would make more sense to the Arabic population.
- P4: the phrase ‘swallowing huge amount of food’ is used as body shaming in Arabic culture, therefore, it was changed into ‘mouthful’.

Naïve translator, T2 – Hanan Al-Alawi

As an individual with non-expert knowledge in medicine and speech-language pathology, I encountered several linguistic issues while translating the questionnaire. They are as following:

- The term “inventory” in the title is vague; does it signify a list, an index or a scale to assess dysphagia? After much deliberation, I decided to translate it as an index that evaluates swallowing problems.
- The first sentence in the introductory paragraph could be simplified to “This questionnaire aims to document your swallowing experience.”
- It is worth mentioning that the term “swallowing” is generally understood as the act of deglutition when the food or drink reaches the pharynx. However, while translating the questionnaire, I realized that medically, the swallowing process begins from the mouth, not the pharynx. Clarifying the term might be beneficial to those who will fill out the questionnaire.
- The term “exclusion” in the last question could be translated into several words in Arabic; I used a strong word to emphasize the isolation of people suffering from swallowing issues from their surroundings.
- The term “upset” in the questionnaire is ambiguous in Arabic as well. I used a blanket term to signify feelings of frustration, irritation, anxiety and anger.

Synthesis process results:

Item number/location	Original	Translated	Rational
Intro and throughout the whole questionnaire	Swallowing	Eating, drinking and swallowing	To indicate the oral phase in addition to the pharyngeal phase
E7	Self-conscious	Anxious	Easier to understand in Arabic
E4	Upset	Discontent	The term upset is strong in Arabic
E6	Self-esteem	The term confidence was added	-New concept -Strong
P4	Swallowing a huge amount of food	Mouthful	-Confusing -Body shaming
F4	Exclusion	Isolation	Strong term
Response categories	No opinion	Don't know	Used in other Arabic questionnaires

Back translation 1: Khadijah Dashti (blinded to the original MDADI, with no HNC expertise).

الملاحظات:

1- يفضل لو كانت ترتيب الأسئلة متدرجة ومتسلسلة بحيث أن الأسئلة المتعلقة بتأثير المشكلة على الحياة الاجتماعية تلي بعضها البعض ومن ثم الأسئلة المتعلقة بتأثير المشكلة على المشاعر الشخصية تكون متتالية والأسئلة المتعلقة بالأنشطة اليومية تكون متتالية وهكذا.
2- الجدول غير واضح! كيف يتم اختيار الجمل؟ هل توضع علامة صح؟ وأين؟ أم يتم الإحاطة بالجمل؟

Translation

Comments:

1. It is preferable to put the questions in a sequence depending on their aim, for example: questions related to the effect of the problem of social life should all be in sequence and then the emotional questions etc.

2. I don't think that having the questions in a table is beneficial. The presentation of the questionnaire should not be in a table. Do patients tick their answer? Or circle it?

Back translation 2: Reem Al-Ali (blinded to the original MDADI, with no HNC expertise). No comments

Results from cognitive debriefing:

Demographics:

- Total of n= 12 HNC patients participated in the cognitive debriefing (6 males and 6 females).
- Mean age = 49 years (22 – 72), with oral, pharyngeal, and laryngeal cancers (nasopharynx was the highest), with varied tumour stages (early to advance).
- All patients were consuming food orally, and time since last treatment was from 0 to 8 years.

Comprehension:

- All participants declared that the questionnaire was easy to understand, and that the questions were not confusing and very relatable.
- The participants thought that adding the terms eating and drinking to the term swallowing is better than having the term swallowing alone, as it may be misinterpreted.
- When asked about the terms 'anxious', 'discontent', 'mouthful', and 'isolation' participants seemed to understand what the intended meaning is.

Retrieval:

- Participants thought that the one week interval was very appropriate, however, some of them admitted that they mixed up past experiences with their current experience.

Judgement:

- Participants thought it was easy to judge the questions, and arrive to answers because it is their own difficult experience, so it was not hard to remember.

Response:

- Participants found it easy to select an answer from the given options and that they all made sense, however, two participants suggested reducing the number of options to three and make it (Always, sometimes, and never) to reduce confusion.
- Participants were asked about the response 'I don't know' and what it means to them, and if they would prefer to change it to 'no opinion' as the response in the original questionnaire. They thought that it makes more sense, as they cannot not have an opinion regarding their own situation.

Other comments by participants:

- One participant suggested adding a question about xerostomia, and one about controlling the bolus in the mouth, however, no changes were made because this was not a general request.
- Regarding the negation: 5 of the participants did not notice the negation in question E7, in comparison to only 2 who did not in question F2.
- In general, participants thought that the questionnaire was easy, non-offensive, and very relatable.
- Most participants admitted that they did not read the introduction.

Comments and recommendations by the investigator:

- In the Arabic version, the statement of '**last week**' in the introduction was underlined and made **bold** or highlighted to attract the participants attention if they do not read the introduction.
- Regarding the negation in questions E7 and F2, no changes will be made at this stage to unify to language in the questionnaire, however, decision will be made after testing the questionnaire to validate its psychometric properties.

Appendix I: Patient information sheet and consent form for the MDADI study (English)

INFORMATION SHEET AND CONSENT FORM

INTRODUCTION & INFORMATION REGARDIGN THIS BOOKLET

- **Name of principal investigator:** Jenan Altamimi
- **Name of organization:** Newcastle University – United Kingdom
- **Sponsors:** Ministry of Health – Kuwait

This booklet has three sections:

1- Information sheet (to share the project information with you).
2- Certificate of consent for the participant.
3- Certificate of consent for the researcher (you need to sign this to indicate your approval).

PART 1: INFORMATION SHEET

INTRODUCTION

My name is Jenan Altamimi, I am a speech and language therapist from Kuwait. I am doing my PhD at Newcastle University – United Kingdom. I hope to help with eating and drinking problems that are very common with head and neck cancer.

I would like to invite you to take part in my research. Please note that you do not have to take part in this research, and you do not have to decide today. Also, feel free to talk with anyone you feel comfortable with about taking part in this research.

If at any point you feel that you need more clarification, you can ask me about it. If you have any questions or concerns at a later stage, I would still be happy to take the time and discuss with you.

PURPOSE OF RESEARCH

Head and neck cancer causes problems in eating, drinking and swallowing foods and drinks. These problems can be as a result of the tumour itself, or because of treatment. Eating and drinking problems can cause many complications that impacts quality of life. In Kuwait, there is currently no questionnaire that aims to capture how swallowing problems in head and neck cancer impact quality

of life in Arabic and in English. Moreover, the results from this questionnaire will help us understand the relationship between dysphagia and quality of life in Kuwait.

TYPE OF RESEARCH

This research involves you filling-out four questionnaires. All four questionnaires are concerned with quality of life for head and neck cancer patients.

PARTICIPANT SELECTION

You are being invited to take part in this research because you have/or have had head and neck cancer.

VOLUNTARY PARTICIPATION

Please note that your participation in this research is voluntary. You are not obliged or under any form of pressure to take part in this research. If you participate, you have the complete freedom to withdraw at any point without providing reasons. You may be asked why you want to withdraw from the research, but you do not have to answer. Whether you participate or not, the services you receive in the centre will continue and will remain unaffected.

PROCEDURE

If you decide to take part in this research, you will be asked to fill-out four questionnaires that will be given to you in a booklet. If you feel uncomfortable answering one of the questions, you can skip and move to the next question. Before you fill-out the questionnaire, the primary investigator will evaluate your oral intake by asking you simple questions. You may be asked to re-fill some questionnaires.

All information are confidential. You will be given a code to identify you, so no one else except me will be able to attribute any of the results to you.

DURATION

It may take between 30 to 60 minutes to fill-out the questionnaires, however, you are under no obligation or any pressure to complete the questionnaires at a certain time.

RISKS

We did not identify any risks that may be associated with you answering the questionnaire. But if at any point you become distressed, please let me know so we can address you concerns and/or terminate the session.

BENEFITS

You may feel that there is no direct benefit to you, however, your participation is likely to help us form a better understanding of quality of life related to eating and drinking difficulties in head and neck cancer by making a patient reported outcome measure available for patients to fill-out routinely.

CONFIDENTIALITY

If you take part in this research, your information and details will not be shared with anyone outside the research team. All information collected will be kept private. Any information about you will have a code instead of your name. Only the research team will know what your code is.

SHARING THE RESULTS

All information you share with us will not be shared with anybody outside the research team, and nothing will be attributed to you by name. The information gathered will be for a PhD research, and results may be disseminated in scientific journals and meeting so that other people who are interested in the topic may learn from the results.

RIGHT TO REFUSE OR WITHDRAW

You do not have to take part in this research. Whether you decide to participate or not, your decision will not affect the services you receive. If at any time you feel that you want to withdraw from the research, you can do so without any concerns.

ETHICAL APPROVAL

This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee. This committee contains members who are

internal to the Faculty, as well as one external member. This study was reviewed by members of the committee, who must provide impartial advice and avoid significant conflicts of interests.
The study was also approved by the research and ethics committee and the Ministry of Health – Kuwait.

WHO TO CONTACT

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact me on the following: Email: J.altamimi2@newcastle.ac.uk

PART 2: CERTIFICATE OF CONSENT – PARTICIPANT

Please read the following statements, and initial box where appropriate:

1. I confirm that I have read and understood the foregoing information, or it has been read to me, and that I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without having to provide any reason, and that whether I participate or not, will not affect the services I receive in the Kuwaiti Cancer Control Centre.

3. I wish to be contacted to participate in future studies.

Participant's name:

Date (dd/mm/yyyy):

Signature:

PART 3: CERTIFICATE OF CONSENT – RESEARCHER

Please read the following statements, and initial box where appropriate:

1. I confirm that I have read and understood the foregoing information, or it has been read to me, and that I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without having to provide any reason, and that whether I participate or not, will not affect the services I receive in the Kuwaiti Cancer Control Centre.

3. I wish to be contacted to participate in future studies.

Participant's name:

Date (dd/mm/yyyy):

Signature:

Appendix J: A-MDADI and original MDADI

مقياس ام دي اندرسون لصعوبات البلع

يهدف هذا الاستبيان إلى تقييم قدرتك على تناول وبلع الطعام والشراب، ستساعدنا هذه المعلومات على فهم شعورك نحو البلع.

ذكرت الإفادات التالية من قبل أشخاص يعانون من صعوبة البلع، قد تنطبق بعضها عليك.

يرجى قراءة كل عبارة واختيار الإجابة التي تمثل تجربتك في **الأسبوع الماضي**.

صعوبة تناول وبلع الطعام والشراب تحد من قدرتي على ممارسة أنشطة حياتي اليومية.

	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
E2	أشعر بالأحراج من عاداتي في الأكل.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
F1	يجد الآخرون صعوبة في إعداد الطعام لأجلي.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
P2	يصبح تناول وبلع الطعام والشراب أكثر صعوبة في نهاية اليوم.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
***E7**	لا أشعر بالتوتر عندما آكل.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
E4	أشعر بالاستياء من مشكلتي في تناول وبلع الطعام والشراب.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
P6	يتطلب تناول وبلع الطعام والشراب مجهودا كبيرا				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
E5	لا أخرج من المنزل بسبب مشكلتي في تناول وبلع الطعام والشراب				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
F5	تسببت صعوبة تناول وبلع الطعام والشراب بخسارة دخلي (راتبي).				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة

P7	استغرق وقتا أطولا في تناول الطعام بسبب صعوبة البلع التي أعاني منها				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
P3	يسألني الناس: " لم لا تستطيع تناول ذلك الصنف من الطعام والشراب؟"				
	أوافق بشدة	أوافق	محايد	لا أوافق	لا أوافق بشدة
E3	ينزعج الآخرون من مشكلتي في تناول وبلع الطعام والشراب.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
P8	أسعل (أكح) عندما أحاول شرب السوائل.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
F3	مشاكلي في تناول وبلع الطعام والشراب تحد من ممارستي لحياتي الاجتماعية والشخصية				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
***F2**	أستطيع الخروج لتناول الطعام والشراب مع أصدقائي، جيراني وأقاربي بأريحية				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
P5	أتناول كمية محدودة من الطعام والشراب بسبب مشكلتي في البلع.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
P1	لا أستطيع المحافظة على وزني بسبب مشكلتي في البلع.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
E6	تقديري لذاتي وثقتي بنفسي أقل بسبب مشكلتي في البلع				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
P4	أشعر بأنني أقوم ببلع كمية كبيرة من الأكل (لقمة كبيرة) أثناء تناول الطعام.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة
F4	أشعر بالانعزال بسبب عاداتي في تناول وبلع الطعام والشراب.				
	أوافق بشدة	أوافق	لا أعلم	لا أوافق	لا أوافق بشدة

شكرا لإجابتكم على هذا الاستبيان!

The M.D. Anderson Dysphagia Inventory

This questionnaire asks for your views about your swallowing ability. This information will help us understand how you feel about swallowing.

The following statements have been made by people who have problems with their swallowing. Some of the statements may apply to you.

Please read each statement and circle the response which best reflects your experience in the past week.

My swallowing ability limits my day-to-day activities.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

E2. I am embarrassed by my eating habits.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

F1. People have difficulty cooking for me.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

P2. Swallowing is more difficult at the end of the day.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

*E7. I do not feel self-conscious when I eat.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

E4. I am upset by my swallowing problem.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

P6. Swallowing takes great effort.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

E5. I do not go out because of my swallowing problem.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

F5. My swallowing difficulty has caused me to lose income.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

P7. It takes me longer to eat because of my swallowing problem.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

P3. People ask me, “Why can’t you eat that?”

Strongly Agree Agree No Opinion Disagree Strongly Disagree

E3. Other people are irritated by my eating problem.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

P8. I cough when I try to drink liquids.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

F3. My swallowing problems limit my social and personal life.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

*F2. I feel free to go out to eat with my friends, neighbours, and relatives.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

P5. I limit my food intake because of my swallowing difficulty.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

P1. I cannot maintain my weight because of my swallowing problem.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

E6. I have low self-esteem because of my swallowing problem.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

P4. I feel that I am swallowing a huge amount of food.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

F4. I feel excluded because of my eating habits.

Strongly Agree Agree No Opinion Disagree Strongly Disagree

Thank you for completing this questionnaire

Appendix K: Summary of the original and translated MDADIs, including the Arabic version

Domain	Original MDADI	Italian MDADI	Swedish MDADI	Brazilian MDADI	Korean MDADI	Dutch MDADI	Arabic MDADI
Sample characteristics	HNC n = 100	HNC n = 50 mean age 65	HNC n = 85 Neuro n = 30 Controls n = 115 Mean age 63	HNC n = 72 mean age 63	HNC n = 33 mean age 61	HNC n = 76 mean age 64	HNC n = 54 mean age 50
Questions	20 questions, two negative questions	20 questions, two negative questions	20 questions, two negative questions	20 questions, all affirmative	20 questions, two negative questions	20 questions, all affirmative	20 questions, two negative questions
Internal consistency	Composite: 0.96	Composite: 0.91 Emotional: 0.83 Functional: 0.85 Physical: 0.85	Composite: 0.88 Emotional: 0.8 Functional: 0.68 Physical: 0.74	Composite: 0.8 Emotional: 0.8 Functional: 0.7 Physical: 0.7	Composite: - Emotional: 0.78 Functional: 0.79 Physical: 0.88	Composite: 0.94 Emotional: 0.86 Functional: 0.82 Physical: 0.87	Composite: 0.93 Emotional: 0.82 Functional: 0.72 Physical: 0.9
Floor and ceiling effects	-	-	Floor: none Ceiling: Global	-	-	None	Floor: none Ceiling: global & functional
Test-retest reliability	**ICC values:** Global: 0.69 Emotional: 0.88 Functional: 0.88 Physical: 0.86	**Pearson r:** Composite: 0.82 Global: 0.43 Emotional: 0.96	**ICC values:** Composite: 0.95 Global: 0.83 Emotional: 0.93	**ICC values:** Composite: 0.79	**ICC values:** Composite: 0.95 Global: 0.82 Emotional: 0.87	**ICC values:** Composite: 0.96	**ICC values:** Composite: 0.93 Global: 0.82 Emotional: 0.92

		Functional: 0.93 Physical: 0.95	Functional: 0.97 Physical: 0.94		Functional: 0.83 Physical: 0.83	Functional: 0.88 Physical: 0.89
Validity	Criterion validity: PSS-eating and diet. Construct validity: SF-36 & Known-group validity	Clinical validity: known-group differences		Construct validity: HAD-D, SWAL-QOL & UW-QOL	Criterion validity: SWAL-QOL	Construct validity: A-DHI and A-EORTC-HN35

Continue: Summary of the original and translated MDADIs, including the Arabic version

Domain	Original MDADI	Arabic MDADI	French MDADI	Chinese MDADI	Danish MDADI	Japanese MDADI	Spanish MDADI
Sample characteristics	HNC n = 100	HNC n = 54 mean age 50	HNC n = 42 mean age 66.4 Controls n = 77	HNC n = 66 median age 62	HNC n = 64 mean age 67	HNC n = 72 Mean age 64	HNC n = 69 Mean age 67
Questions	20 questions, two negative questions	20 questions, two negative questions		20 questions all affirmative	Total 24 questions, only the original 20 were included in the analysis, two negative questions	20 questions, two negative questions	20 questions, two negative questions
Internal consistency	Composite: 0.96	Composite: 0.93 Emotional: 0.82 Functional: 0.72 Physical: 0.9	Composite: 0.84	Composite: 0.93 Emotional: 0.84 Functional: 0.82 Physical: 0.83	Composite: 0.95 Emotional: 0.91 Functional: 0.87 Physical: 0.88	Composite: 0.92 Emotional: 0.67 Functional: 0.81 Physical: 0.83	Composite: 0.9
Floor and ceiling effects	-	Floor: none Ceiling: global & functional	-	-	Floor: global Ceiling: global, functional, physical, & emotional	-	None

Test-retest reliability	**ICC values:** Composite: NA Global: 0.69 Emotional: 0.88 Functional: 0.88 Physical: 0.86	**ICC values:** Composite: 0.93 Global: 0.82 Emotional: 0.92 Functional: 0.88 Physical: 0.89	Spearman rho = 0.84 for the composite score	ICC: 0.72	**ICC values:** Composite: 0.98 Global: 0.95 Emotional: 0.95 Functional: 0.94 Physical: 0.95	**ICC values:** Composite: 0.84 Global: 0.58 Emotional: 0.78 Functional: 0.79 Physical: 0.81	**ICC values:** Composite: 0.98 Global: - Emotional: 0.91 Functional: 0.9 Physical: 0.94
Validity	Criterion validity: PSS-eating and diet. Construct validity: SF-36 & Known-group validity	Construct validity: A-DHI and A-EORTC-HN35	External & known-group validity	Criterion validity: SWAL-QOL Construct validity: HADS, FOIS & Known-group validity	-	Discriminant validity (Known-group difference) Concurrent validity (EORTC-HN35)	Construct validity: SF-12

Appendix L: Vignettes examples and food glossary and gallery

Rating instructions:

Functional oral intake:

Clinicians may obtain information from a variety of sources including medical charts, dietary journals, and/or verified patient reports. Verification of patient records may be obtained from a spouse or family members or from a variety of sources for institutionalised patients.

Normalcy of diet:

'Begin by asking the patient what kinds of foods (s)he has been eating. Ask what foods are difficult to eat. Based on the patient's response, choose an item at the low end of the scale. Move up the scale giving examples of foods in each category and asking the patient if (s)he is eating those food items. Even if the patient says that (s)he eats everything, inquire about specific items beginning with 50, soft chewable foods and moving upwards. Stop at the item which the patient cannot eat. The patient then receives the score **below** that. If the patient indicates that (s)he is eating a full diet, also inquire whether (s)he needs to drink more liquids than usual with meals; eating a full diet with intake of extra fluids is scored 90. If the patient can take foods orally, but is also using a feeding tube, score based on solid food'.

For the purpose of this study, information must be obtained from the case vignettes and the dietary journals.

Case: Laryngeal cancer

Fawzyah, a 61 year-old ex-smoker completed her radiation treatment with full recovery 15 months ago. She's trying to maintain a balanced diet, and her major concern is xerostomia. She drinks from 2 -3 litres of water per day. When asked about her eating habits and diet, this is what she provided in her diet-journal:

Day 1:	**Day 2:**	**Day 3:**
Breakfast: Cheese with tomatoes, Arabic bread[4] and tea with milk. **Lunch:** Mutton machbous[7] + salad. **Snack:** dates + Arabic coffee. **Dinner:** Yogurt with fruits.	**Breakfast:** Pancakes + apple juice. **Lunch:** Hamour stew[5] + white rice + salad. **Snack:** Turkish coffee + cake slice. **Dinner:** Soup.	**Breakfast:** Shakshouka[6] + Arabic bread + tea. **Lunch:** Pasta with red sauce and veggies + Lemonade. **Snack:** Parfait + coffee. **Dinner:** Salad

Case: Nasopharynx cancer

Bayani, a 61 year-old male patient known to have diabetes, is currently undergoing chemoradiotherapy treatment for his locally advanced nasopharyngeal cancer. At baseline, Bayani complained of difficulties in swallowing. He received a prophylactic Percutaneous Endoscopic Gastrostomy (PEG) tube prior his treatment. His blood sugar is being managed, and he suffers from appetite loss and nausea in addition to his dysphagia. His three day diet journal is as follows according to his attending nurse:

Day 1:	**Day 2:**	**Day 3:**
Morning: Enteral formula through PEG Normal saline. **Afternoon:** Yogurt with honey + water **5 pm:** Soup. **Dinner:** Enteral formula through PEG Normal saline.	**Morning:** Enteral formula through PEG Normal saline. **Afternoon:** Vegetable soup + water **4 pm:** Mashed potatoes + diabetic custard. **Dinner:** Enteral formula through PEG Normal saline.	**Morning:** Enteral formula through PEG Normal saline. **Afternoon:** oats with milk + water **6 pm:** chicken soup. **Dinner:** Enteral formula through PEG Normal saline.

Case: Nasopharynx cancer

Osama, a 57 year-old male was diagnosed with cancer of the nasopharynx in 2016 (two years ago). He was treated effectively by radiotherapy. During, and approximately six months after his treatment he complained of some degree of dysphagia and xerostomia. However, he claims that he is managing well right now, and that he is trying to lose some weight. When asked about his three-day diet journal, this is what he provided:

Day 1:	**Day 2:**	**Day 3:**
Breakfast: two scrambled eggs with Arabic bread and a cup of coffee. **Snack 1:** dates and Arabic coffee. **Lunch:** Fish stew with small cup of rice + mixed veggies. **Dinner:** Soup.	**Breakfast:** white cheese, olives, tomatoes and cucumber with Zaatar[13] + ½ Iranian bread[14] + cup of tea. **Lunch:** Harees[15]. **Snack:** Mixed fruits. **Dinner:** left over Harees.	**Breakfast:** Labnah[16] with zaatar and Arabic bread + orange juice. **Lunch:** Momawash[17] + tomato sauce + veggies. **Snack:** Basboosa[18] + tea **Dinner:** Soup + yogurt and cucumber.

Example of food dictionary:

1	Rigag bread	Wafer-thin bread
2	Foul mudammas	Cooked fava beans with olive oil, tomatoes and onions.
3	Om Ali	Dough and nuts cooked in milk and cream
4	Arabic bread	Pitta bread
5	Hamour stew	Fish cooked in tomato sauce with veggies and herbs
6	Shakshouka	Eggs poached in tomato sauce, chilli and onions with spices
7	Machboos	Fragrant rice that has been cooked in well-spiced chicken/mutton broth, accompanied with chicken/mutton and hashu (onions, raisins and chickpeas)
8	Leban	Curd based drink
9	Dal	Lentils cooked with curry sauce
10	Halva	Dense and sweet confection
11	Misal Pav	Curry made from sprouted moth beans and Indian bread roll
12	Dal Makhni	Beans with butter and cream

Example of photos gallery:

1 Rigag bread

2 Foul mudammas

3 Om Ali

4 Arabic bread

5 Hamour stew

6 Shakshouka

7 Machboos

8 Leban

9 Dal

10 Halva

11 Misal pav

12 Dal Makhni

Appendix M: Participant information sheet and consent form for the cognitive interviews

INFORMATION SHEET

WHAT IS THE PURPOSE OF THE RESEARCH?

This study aims to assess and explore the acceptability and clinicians' views on two validated diet scales, the Functional Oral Intake (FOIS) and the Performance Status Scale (PSS – Normalcy of diet).

WHO IS DOING THE RESEARCH?

- **Name of principal investigator:** Jenan Altamimi – Speech and language therapist.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

Funding body: Ministry of health – Kuwait.

Organisation body: Newcastle University – United Kingdom

WHY DID YOU CHOOSE ME?

You are being invited to take part in this research because you are currently working, or have worked with swallowing problems associated with head and neck cancer (HNC).

DO I HAVE TO PARTICIPATE?

No. Whether you choose to participate or not is completely up to you and no one will know about your decision. You also have the right to withdraw at any time without giving reasons.

WHAT DO I HAVE TO DO IF I DECIDE TO PARTICIPATE?

- Sign a consent form.
- Rate 10 typical HNC cases on two scales while thinking aloud, and then participate in a follow-up interview (Time required: 45 to 60 minutes).

ARE THERE ANY RISKS OF ME TAKING PART?

No risks were identified.

ARE THERE ANY BENIFTS FOR ME IF I TAKE PART?

There may not be a direct benefit to you, but your participation will help us provide a scale that assess dietary restrictions for HNC patients in Kuwait.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH?

This research is part of a PhD study, the results may be published in scientific meetings or journals. All results will be kept confidential and nothing will be associated with your name. If you wish, you can have a summary of the results once the study is complete.

WHO TO CONTACT IF I HAVE A PROBLEM?

If you have any problems or concerns, you can reach me on:

Email: J.altamimi2@ncl.ac.uk – Jenan.altamimi1@gmail.com

Thank you for taking time to read this
and for considering your participation in the study!

CERTIFICATE OF CONSENT

Please read the following statements, and initial box where appropriate:

1. I confirm that I have read and understood the information sheet, or it has been read to me, and that I have had the opportunity to ask questions, and any questions I have asked have been answered to my satisfaction.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without having to provide any reason.

3. I agree to be audio-recorded for the interview.

Participant's name:

Date (dd/mm/yyyy):

Signature:

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