PATIENT INFORMATIONAL NEEDS CONCERNING ORAL EPITHELIAL DYSPLASIA

Abdullah Alsoghier, PhD candidate (clinical experience)

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Supervised by

Prof Stephen Porter

Prof Stefano Fedele

Dr Richeal Ni Riordain

DECLARATION

I, Abdullah Mohamed Alsoghier confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

[redacted]

Abdullah Alsoghier

Department of Oral Medicine

UCL Eastman Dental Institute

London, United Kingdom

ABSTRACT

Patient education through clinician-patient health information exchange is essential in the clinical care of people with chronic and pre-malignant diseases such as, perhaps, the oral epithelial dysplasia (OED). The literature review found a knowledge gap on what information an individual with OED may want or considered important, a lack of specific instrument that can be used to assess the patient's information needs (IN) and a shortage of studies available on whether individuals with OED would exhibit higher prevalence of symptoms, that can be experienced with cancer-linked conditions, including the anxiety and depression, dental anxiety and poorer oral health-related quality of life (OHQoL) compared to the general population or those with other chronic diseases.

Thus, the study aimed to (1) assess what information patients would find when they search the Internet, (2) identify instruments that can be helpful to develop an IN instrument, (3) develop and determine the psychometric properties of the new IN instrument for OED (ODIN-Q), (4) assess the IN about OED using ODIN-Q, (5) determine the patient-clinician concordance on this information, (6) assess the prevalence of anxiety and depression, dental anxiety and OED impact on OHQoL and (7) develop and assess a patient information leaflet on OED.

The analyses of the web indicated a shortage of content with the presented content being of low quality, poor understandability and actionability and challenging to read. The newly developed IN instrument (ODIN-Q) showed adequate psychometric properties and indicated that 52% of patients had unmet IN. Clinicians predicted the highest important information to patients. However, they exhibited poor prediction on

its importance. The prevalence rates for symptoms of anxiety, depression and emotional distress at 30%, 16% and 26%, respectively. While dental anxiety levels were like those in a general population, OHQoL scores were notably higher. The newly developed leaflet was found to be acceptable and readable by most of the respondents.

IMPACT STATEMENT

The present project shows several approaches and findings that can contribute to a meaningful impact on the education and clinical care for patients with OED, clinicians and health care researchers.

Patient participation was vital in the development and validation of a patient-reported experience measure (ODIN-Q). The collected information led to a patient information leaflet that was tailored to their needs and preferences. Patients also helped in the preliminary and final assessments of the acceptability and readability of this leaflet. If an individual understands and is able to remember its content, it can improve his/her ability to make informed decisions related to OED or its treatment and recognising the worrisome symptoms of recurrent or progressive OED lesions. It can also help to reduce identifiable risk behaviours (i.e. tobacco use, alcohol consumption, betel leaf and areca nut), which in turn, can minimise the biological events that increase the short- and/or long-term risk of malignant transformation.

Clinicians (e.g. oral medicine and oral surgeons) can use ODIN-Q before consultations, as part of their clinical care, to increase the effectiveness and impact of their communication with their patients. The gathered information can be used to produce tailored patient educational materials on the disease and/or its treatment following the guidelines, toolkits and assessments highlighted in the present project. They may also consider assessing anxiety and depression, dental anxiety and OHQoL and consider interventions and referral to specialists for those presenting increased or deteriorated levels. Researchers, in turn, can adapt ODIN-Q or following its methods of development to assess IN concerning other diseases and clinical procedures.

Some study findings (chapter one) were published in a peer-reviewed journal with high impact factor and has been cited six times since its publication by studies highlighting the importance of developing sources of information for patients with oral potential malignant disorders (Panta et al., 2018), a nutrition guidance for patients with cancer (Keaver et al., 2020) and studies on the available web content of different health conditions. Also, the findings of the previous chapter, along with those of chapter 3, were presented in two peer-reviewed oral medicine conferences. Other sections related to the validation of ODIN-Q and patient-clinician concordance on information concerning OED (chapter 3-4), anxiety and depression, dental anxiety and OHQoL (chapter 5) and development of the new PIL (chapter 6) will be submitted to scholarly journals. The developed patient information leaflet about OED will be available at the outpatient Oral Medicine clinics at UCLH and the UCLH e-library, which can be accessed by all users (patients) who have access to this library.

Future research may, however, consider overcoming the limitations of the present project by adopting a mixture of quantitative and qualitative approaches for assessing IN, longitudinal IN assessments to evaluate the overtime changes and evaluate the responsiveness, maintain adequate sample size through multi-centre recruitment especially for a disease with low prevalence such as the OED and assessing different print and audio-visual formats of patient educational materials to see whether a patient would prefer one over others.

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LIST OF ABBREVIATIONS

AMA	American Medical Association
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments
DA	Dental anxiety
EFA	Exploratory factor analysis
FRES	Flesch Reading Ease Score
FKGL	Flesch-Kincaid Grade Level
FWCI	Field-Weighted Citation Impact
HADS	Hospital Anxiety and Depression scale
HCPs	Health care professionals
HNC	Head and neck cancer
HON	Health on the Net
HPV	Human papilloma virus
IF	Impact factor
IN	Information needs
JAMA	Journal of the American Medical Association
KHOS	Krantz Health Opinion Survey
LOC	Locus of control
MDAS	Modified Dental Anxiety Scale
MT	Malignant transformation
NHS	The UK National Health Service
OC	Oral cancer
ODIN-Q	Oral epithelial dysplasia informational needs questionnaire
OHI	Online health information
OED	Oral epithelial dysplasia

OHIP-14	Oral Health Impact Profile-14
OL	Oral leukoplakia
OLP	Oral lichen planus
OSF	Oral submucous fibrosis
OSCC	Oral squamous cell carcinoma
OPMDs	Oral potential malignant disorders
PEMAT	The Patient Education Material Assessment Tool
PIL	Patient information leaflet
PREM	Patient reported experience measure
PROM	Patient reported outcome measure
OHQoL	Oral health-related quality of life
QoL	Quality of life
TINQ-BC	Toronto Informational Needs Questionnaire for Breast Cancer
UCLH	University College London Hospitals
WHO	The World Health Organisation

PUBLICATIONS FROM THE PRESENT THESIS

Journal articles

1. Alsoghier, A., Riordain, R.N., Fedele, S. and Porter, S., 2018. Web-based information on oral dysplasia and precancer of the mouth–Quality and readability. Oral oncology, 82, pp.69-74.

Abstracts presented in peer-reviewed conferences

1. Alsoghier, A., Riordain, R.N., Fedele, S. and Porter, S. 2018. Assessment of Patient-Oriented Online Information of Oral Epithelial Dysplasia. *The American Academy of Oral Medicine*. San Antonio, USA (https://www.aaom.com/assets/docs/2018_Conference/AAOM%202018%20Poster%20Abstracts%20v.3.13.18(1).pdf).
2. Alsoghier, A., Riordain, R.N., Fedele, S. and Porter, S. 2019. Information needs of patients with oral epithelial dysplasia. *The American Academy of Oral Medicine*. New Orleans, USA (https://www.sciencedirect.com/science/article/pii/S2212440319314683).

INTRODUCTION

Oral epithelial dysplasia (OED) is a histopathological finding associated with an increased risk of oral squamous cell carcinoma development (OSCC) (Ho et al., 2012, Speight et al., 2018, Iocca et al., 2019). It is estimated that OED affects 2.5 to 5 individuals of 1000 of the population (Mehanna et al., 2009) and carries a risk of OSCC between from 6% and 36% (Field et al., 2015). Clinically, OED can present in the context of oral potentially malignant disorders (OPMDs) (Jin et al., 2016), which include leukoplakia, erythroplakia, lichen planus, actinic cheilitis, discoid lupus erythematous, and some inherited cancer syndromes (Warnakulasuriya et al., 2007, Sarode et al., 2011, Muller, 2018). In the UK, OSCC is among the 15 most common cancers, with approximately 6,000 new cases per year (Cancer Research UK, 2017).

BACKGROUND AND RATIONALE

A substantial body of literature has highlighted the importance of patient education and the provision of information in shared-decision making and management of chronic and premalignant disease (Lim et al., 2007, Ankem, 2015, Grilo et al., 2017) such as perhaps OED. For example, it has been suggested that patients with lesions suspicious of cervical cancer may not be satisfied with the information provided by healthcare professionals, despite the extensive nature of the material provided (Palmer et al., 1993, Hellsten et al., 2008). Similarly, having unmet informational needs (IN) among those with OPMD was correlated with higher anxiety levels (Lin et al., 2015), which in turn could affect the patient’s well-being and compliance with the treatment provided (DiMatteo et al., 2000).

Overcoming these undesirable health outcomes requires the delivery of tailored and patient-centred care that provides information based on patient’s actual needs and preferences (Luker et al., 1995, National Institute for Clinical Excellence, 2012, Foster et al., 2015, Kassianos et al., 2016). One increasingly common method to do so is to acquire this information by an informational needs (IN) scale (Halkett et al., 2007, Dall'Armi et al., 2013, Alamanou et al., 2016). These scales have been developed for a range of medical conditions including chronic disorders and some cancers, but none of these are known to be suitable to assess the need for information for OED specifically. Hence, a specific and culturally sensitive tool to determine the informational needs and preferences of patients with OED may help to achieve these objectives effectively. The data collected by this tool may help to acknowledge the impact of the illness on physical and psychological well-being. Furthermore, this data could be used to generate a source of OED patient-focused information (such as a patient information leaflet) that genuinely reflects the IN of this patient population.

LITERATURE REVIEW

A narrative overview of the current literature related to oral epithelial dysplasia (OED), information needs (IN) and available IN instruments was accomplished to construct the overall theme of this project. This performed by searching the following biomedical databases: University College London library database, PubMed, Scopus, Google Scholar, and Cochrane library published in English from January 1900 to January 2020. The following searching terms used:

1. Oral epithelial dysplasia OR oral dysplasia OR oral precancer.
2. Oral dysplasia AND (information needs OR patient education OR health information OR patient needs OR quality of life OR anxiety OR depression).
3. Information* needs OR information* needs instrument OR information* needs tool.

The title and abstract of the eligible articles were screened, and the full text of relevant content was extracted. Also, a manual search of references of the included publications was performed as well.

Oral epithelial dysplasia

Background

Oral epithelial dysplasia (OED) is a histological finding associated with an increased risk of malignant transformation (MT) of the oral epithelium (Ho et al., 2012, Sarode et al., 2014, Iocca et al., 2019). WHO describes the OED as '*a spectrum of architectural and cytological epithelial changes caused by the accumulation of genetic changes, associated with an increased risk of progression to squamous cell carcinoma*' (El-Naggar et al., 2017).

It is estimated that OED affects 2.5 to 5 individuals of 1000 of the population (Mehanna et al., 2009). It could only be detected through histological examination of oral potentially malignant disorders (OPMDs). These disorders can precede oral cancers in up to 70% of cases (Jin et al., 2016). Examples of OPMDs include leukoplakia, erythroplakia, lichen planus, actinic cheilitis, discoid lupus erythematous, and some inherited cancer syndromes (Warnakulasuriya et al., 2007, Sarode et al., 2011, Yardimci et al., 2014).

Oral chronic Graft Versus Host Disease is another disorder that has been linked for developing OED and OSCC in retrospective studies (Mawardi et al., 2011, Kakei et al., 2012, Tsushima et al., 2015, Weng et al., 2017). Also, the inflammatory process in hereditary epidermolysis bullosa may predispose the affected individuals to a higher risk of OSCC, which might be precedented by an earlier OED (Porter et al., 2018). The term 'precancer' is replaced by "potentially malignant" as it implies the possibility of transformation rather than an inevitability (Warnakulasuriya et al., 2007). Similarly, the term 'disorder' is being used rather than 'lesion' as it acknowledges that MT can occur in sites other than where the primary lesion arises (e.g. other mucosal surfaces of oral cavity or upper gastrointestinal tract) (van der Waal, 2014, Edwards, 2018).

Histopathological criteria for the diagnosis of OED

The histopathological examination remains the gold standard to diagnose OED, within the clinically apparent OPMDs, to guide the clinical management and prognosis (Dost et al., 2014, Edwards, 2014, Giovannacci et al., 2016, Warnakulasuriya, 2018). Several histology-based grading systems have been suggested for OED based on non-oral lesions such as neoplasia of cervix and larynx; however, these are limited of use in the oral cavity (Dost et al., 2014).

The eldest grading system classified the mucosa according to the presence of dysplasia as none, slight, or marked dysplasia (Smith et al., 1969). More recent and commonly used system is the 2005 WHO classification, which categorises lesions, based on the degree of cellular atypia, into hyperplasia, mild, moderate, severe, carcinoma-in-situ, or squamous cell carcinoma (Dost et al., 2014, Tilakaratne et al., 2019). Due to the concerns on reproducibility as well as the biological and clinical significance of the latter, the 2017 WHO adopted the binary grading system initially described by Kujan et al., (2006) for OED as low (8077/0) or high grade (8077/2) (Barnes, 2005, Kujan et al., 2006, El-Naggar et al., 2017). The WHO diagnostic criteria based on the histopathological exam are summarised in Table 1.

Table 1 The 2017 WHO diagnostic criteria for OED.

Architecture	**Cytology**
Irregular epithelial stratification	Abnormal variation in nuclear size (anisonucleosis)
Loss of polarity of basal cells	Abnormal variation in nuclear shape (nuclear pleomorphism)
Drop-shaped rete ridges	Abnormal variation in cell size (anisocytosis)
Increased number of mitotic figures	Abnormal variation in cell shape (cellular pleomorphism)
Abnormally superficial mitoses	Increased nuclear-cytoplasmic ratio
Premature keratinization in single cells (dyskeratosis)	Increased nuclear size
Keratin pearls within rete pegs	Increased number and size of nucleoli
Loss of epithelial cell adhesion	Hyperchromasia

Adapted from El-Naggar, A et al. 2017. WHO classification of head and neck tumours. 4th ed. Lyon, France: International Agency for Research on Cancer (IARC).

Other adjunct diagnostic aids for OED

Aside from the biopsy, adjunct diagnostic techniques can be helpful as an aid to initially diagnose OPMDs, however, a limited evidence available to support its use in clinical settings (Sridharan et al., 2012, Yang et al., 2018b). These based on cytology (e.g. oralCDx Brush Test), tissue staining (e.g. toluidine blue) and light-based systems that can be classified based on the light source to (1) ultraviolet and visible spectrum (e.g. Auto-fluorescence spectroscopy) and (2) laser-based systems (e.g. Raman imaging, and Optical Coherence Tomography).

The oral brush biopsy is a non-invasive and valuable diagnostic procedure to rule out OED, however, its diagnostic accuracy has been questioned in several studies (Omar, 2015). Despite its relatively moderate sensitivity (74.1%), the specificity to identify

OED or OSCC was only at 32% (Poate et al., 2004). Toluidine blue is another low-cost and straightforward diagnostic aid that remains a ‘clear winner’ in comparison to the newer diagnostic modalities (Chhabra et al., 2015). Despite its lower reliability with lesions exhibit low-grade dysplasia, it showed high sensitivity in high-grade dysplasia and early OSCC (Martin et al., 1998, Omar, 2015).

Chemiluminescence and tissue autofluorescence imaging systems can also help in detecting OSCC and OPMDs although the evidence is lacking to recommend its applications in primary health care services and concerns toward false negatives of these techniques (Spivakovsky et al., 2015, Huber, 2018). Optical Coherence Tomography (OCT) is using the light to create an ‘image’ that can be assessed to distinguish different grades of OED and SCC from normal oral mucosa (Scully et al., 2008, Wilder-Smith et al., 2009, Lee et al., 2015). OCT was used to characterise mild from moderate OED by using automated image evaluation with 83% sensitivity and 90% specificity (Lee et al., 2012), and SCC from non-SCC lesion as high as 93% for both of sensitivity and specificity in comparison to histological examination (Wilder-Smith et al., 2009). Although OCT technologies have shown promising results yet, prospective studies are needed to validate its applications in clinical practice (Yang et al., 2014).

Progression of OED to oral squamous cell carcinoma (SCC)

There is insufficient evidence available to support using adjuvant diagnostic aids to detect MT and visual examination remains the main method to detect MT of OED (Brocklehurst et al., 2013). The MT of OED varies across different studies according to the study characteristics such as sample size, the grade of dysplasia, and duration of follow-up. It ranges from 6.6% and 36.4% with an average time from 6 months to 17 years (Field et al., 2015). A systematic review and meta-analysis by Mehanna et al. (2009) reported a mean overall MT rate and time of 12.1% and 4.3 years, respectively. The risk of MT is also linked to the dysplasia grade; the 5-year MT risk of severe dysplasia to develop OSCC is at 39%, moderate at 18%, and mild dysplasia at 6% (Sperandio et al., 2013). These results were confirmed with another recent study that showed a higher annual risk of MT of severe OED in comparison to mild OED (3.57% versus 1.7%) (Iocca et al., 2019).

Clinical and molecular factors to predict MT of OED

Although no available clinic-pathological or molecular markers that can truly predict the MT in patients with OPMDs (van der Waal, 2014), figure 1 shows the significant predictors for oral carcinogenesis of these lesions (Mehanna et al., 2009, Warnakulasuriya et al., 2011, Ho et al., 2012, Thomson, 2012, Dost et al., 2014, Thomson, 2015).

Patient charactersitics	Disease charactersitics	Clinical charactersitics
• Older age. • Female gender (controversial) • Non-soker with lesions exhibit OED • Excessive and strong addiction to smoking • Excessive and persistent intake of alcohol • Low socieconomic status. • Material depriviation	• Longer duration • Multiple lesions	• Erythroplakia • Erythroleukoplakia • PVL • Non-homogenous lesions • Lesions with ulceration or erosion • lesion size more than 200 mm² • Lesions on the tongue, gingiva, retromolar area, and floor of mouth • human papilloma virus (HPV) • High-grade OED

Figure 1 The significant characteristics for malignant transformation of OPMDs.

Also, studies have highlighted the role of specific changes within molecular factors in dysregulation of DNA damage response, which acts as a barrier against the MT (Chou et al., 2011, Nikitakis et al., 2018). Tumour protein p53 is one of these factors that has been considered as the most predictive marker for OSCC (Whyte et al., 2002) as well as DNA ploidy and loss of heterozygosity (LOH) (Bell et al., 1999, Sperandio et al., 2013, Gomes et al., 2015). Indeed, LOH at certain chromosomes was detected in dysplasia (3p, 9p, and 17p) and thus can be useful to predict MT in low-grade OED (Pathare et al., 2009, Leemans et al., 2011). Nevertheless, there are no available clinic-pathological or molecular markers that can reliably predict the MT in patients with OPMDs (van der Waal, 2014).

Management of patients with OED/OPMDs

The management of patients with OED lesions has been mainly discussed within the context of their associated clinical and/or histopathological diagnosis of OPMDs (Jerjes et al., 2012a). Also, many of these studies did not differentiate lesions with dysplasia versus those without while investigating different interventions for OPMDs (Lodi et al., 2016). Therefore, the present section is focused on the management of common OPMDs, including oral leukoplakia, oral erythroplakia, oral lichen planus and oral submucous fibrosis (Speight et al., 2018).

In general, there is no consensus on how these should be managed neither robust evidence of the available therapeutic options (Field et al., 2015) or how to reduce or prevent malignant transformation in patients with OPMDs (Dost et al., 2014, van der Waal, 2014, Tilakaratne et al., 2019). A legitimate intervention would depend on the probability of this transformation which might be identified by prognostic clinical, molecular and histopathological markers of each condition and whether this intervention is significantly reducing or preventing the risk (Banerjee et al., 2003, Scully et al., 2008, Field et al., 2015).

Aside from the presence of OED, risk factors include clinical variables such as the presence of red or speckled and non-homogeneous lesions that exceed 200 mm2 and those present in the tongue and floor of the mouth (Speight et al., 2018). In contrast, factors of less correlation included female gender, persons aged above 50 years and some histological/molecular biology findings (e.g. detection of HPV-16 and loss of heterozygosity) (Speight et al., 2018). A further ‘generic’ binary risk stratification (high or low risk) of oral precancerous lesions is presented in Figure 2 (Thomson, 2012).

High-risk category

- Tobacco use
- Excess alcohol consumption
- Use of betel quid
- Predisposing genetic factors and inherent susceptibility
- Immunodeficiency
- Diet low in fresh fruit and vegetables
- Old age
- Marijuana use

Low-risk category

- Low socioeconomic status
- Poor oral health
- Use of shammah/toombak
- Human papillomavirus infection
- Candida albicans infection
- Diabetes mellitus

Figure 2 The binary risk stratification for patients with oral potentially malignant disorders.

Despite the lack of highly reliable evidence, the following interventions are generally of choice of OPMDs: risk behaviour modification (e.g. smoking cessation and reducing alcohol consumption), medical treatment (e.g. carotenoids, lycopene, vitamins [ascorbic acid, alpha-tocopherol and retinoic acid], cytotoxic agents [bleomycin] and non-steroidal anti-inflammatory drugs [celecoxib]) and surgical excision (e.g. cold blade, laser [CO2 and Nd;YAG], cryotherapy and photodynamic therapy) (Jerjes et al., 2012a, Thomson, 2012, Kuribayashi et al., 2015).

A Cochrane review of interventions for oral leukoplakia (OL), which presents an overall malignant transformation rate of 9% and 49% of its verrucous subtype (Iocca et al., 2020), indicated that surgical management was never investigated in randomised clinical trials (Lodi et al., 2016). Whereas limited evidence available to support the effectiveness of systemic medical interventions (vitamin A, beta carotene and lycopene) compared to placebo (Lodi et al., 2016). The previous study also demonstrated the low-quality evidence available to support other interventions such as non-steroidal anti-inflammatory drugs (celecoxib), systemic or topical complementary treatments (vitamin A, C and retinoids), cytotoxic agents (topical bleomycin) and Bowman-Birk inhibitor. Similarly, it is yet unknown if changing oral leukoplakia-associated risk behaviour, such as smoking, is sufficient to prevent the malignant transformation (Lodi et al., 2016). Also, the concerns about the systemic toxicity of retinoids and recurrence of lesions in up to 54% of cases may act as deterrents to recommend its use for OL (Awadallah et al., 2018).

In non-randomised clinical studies, the surgical excision or ablation by laser (CO2) was considered reliable to reduce the recurrence and perhaps the progression of lesions with non-homogenous features and dysplastic changes with fewer post-operative complications than other methods (Jerjes et al., 2012a, Mogedas-Vegara et al., 2016). Further prospective and randomised clinical studies are, however, needed to determine the significance of this modality (Mogedas-Vegara et al., 2016). The management of oral erythroplakia, a less common clinical diagnosis than OL with an overall malignant transformation rate of 33% (Iocca et al., 2020), would often require earlier surgical intervention. Long-term observation is also needed due to the high incidence of epithelial dysplastic and cancerous changes among patients presented with these lesions (Rhodus et al., 2014, Awadallah et al., 2018).

Regarding the oral lichen planus (OLP), topical corticosteroids remain the first line for treatment compared to placebo. They might be, however, slightly less effective for pain management than calcineurin inhibitors (tacrolimus) despite the potential adverse effects of the latter (Lodi et al., 2012, Lodi et al., 2020). Highly reliable evidence is yet lacking on the effectiveness of other calcineurin inhibitors (pimecrolimus), aloe vera and cyclosporin to reduce the pain compared with corticosteroid or placebo (Thongprasom et al., 2011, Lodi et al., 2012).

Low-level laser and photodynamic therapies are becoming reliable alternatives for pain control in patients with symptomatic OLP (Jerjes et al., 2012b, Akram et al., 2018a, Lodi et al., 2020). In patients with erosive and atrophic OLP, a case-controlled study indicated a statistically significant improvement of VAS scores among the low-level laser group compared to topical corticosteroid (triamcinolone) (El Shenawy et al., 2015). Also, a recent prospective case-controlled trial showed that a 4-session treatment with photodynamic therapy led to a significant reduction of the inflammatory activity of OLP and lesion size, and improved the quality of life with some of these effects remain even six weeks after treatment (Cosgarea et al., 2020). Further randomised clinical trials are required to confirm the efficacy and safety of these therapies to manage OLP (Akram et al., 2018a, Akram et al., 2018b).

The management of oral submucous fibrosis (OSF), which presents 5% overall risk of cancer (Iocca et al., 2020), usually includes a combination of treatment modalities based on the disease severity and impact on the quality of life (Warnakulasuriya et al., 2016). The non-surgical interventions for OSF involve the cessation of tobacco chewing (areca nut and betel quid), physical therapy (exercise, splints and microwave diathermy) and medical treatments such as micronutrients and antioxidants (vitamin A and E, lycopene, aloe vera and curcumin), intralesional injection of proteolytic enzymes (collagenase and hyaluronidase) and immune-modulation agents (topical corticosteroids, interferon-gamma and pentoxifylline) (Warnakulasuriya et al., 2016, Rao et al., 2020). In contrast, surgical management can include extra or intraoral flaps and using allografts (Arakeri et al., 2017). Yet, the available treatment protocols for OSF are not necessarily based on robust evidence, and hence, further randomised clinical trials are needed (Arakeri et al., 2017, Rao et al., 2020).

Anxiety and distress in patients with OED

There is little known about the psychological characteristics including anxiety and distress among those with OPMDs and cancer symptoms, which are frequently overlooked, and it is not driven by theory (Scott et al., 2006, Brocken et al., 2012, Noonan, 2014). In general, the diagnosis of OED could influence the patient's QOL (Morse et al., 2010) which was also demonstrated by other studies of suspected cancer conditions affecting the lung (Brocken et al., 2015), breast (Brocken et al., 2012), and colorectal structures (Ndukwe et al., 2012).

The sources of anxiety, depression and distress in OED are multiple and may start from the first realisation of symptoms and referral process to surgical procedures of oral suspicious lesions. The patient during this period could present with increased levels of anxiety, stress, and mood disturbance in addition to reduced levels of immunological cell activity which could persist for weeks or months (Witek-Janusek et al., 2007, Ndukwe et al., 2012, Renzi et al., 2015). Of note, only a small proportion of those who underwent an urgent cancer check is diagnosed with cancer, while more than 80% would receive 'non-cancer' or 'all clear' diagnosis (Renzi et al., 2015). Aside from receiving a positive or false-positive diagnosis, this experience could generate further anxiety and stress that could affect coping with medical management, as shown in cancer patients (Manne et al., 2010).

Another source of anxiety is the associated OPMDs that could affect the quality of life (QOL) by its oral or systemic manifestation. One example is the higher anxiety and depression levels reported among individuals affected by oral lichen planus compared to the general population or patients without the disease (García-Pola Vallejo et al., 2001, Gavic et al., 2014, Pippi et al., 2016, Wiriyakijja et al., 2020). It is also important to consider these variables among patients with concurrent or previous oral cancer. These patients may have undergone surgical procedures that cause significant discomfort due to pain and sharp instruments, worries about incompetent clinicians, post-treatment complications, and financial expenses (Hakeberg et al., 2001, Lopez-Jornet et al., 2012). For instance, 19% to 50% of individuals with oral cancer are affected psychologically (Reisine et al., 2005), which could remain in 22% to 32% of them even ten years after the primary diagnosis (Espie et al., 1989).

Interestingly, only one study reported lower depression levels at the time of diagnosis of OED than others reported in community-based studies and oral cancer (Reisine et al., 2005). However, the collected samples of the previous survey were from community-based dental practices in which oral cancer diagnosis is more likely to be at an early phase with improved prognosis. Also, measuring these was by scoring instrument (CES-D) rather than a clinical diagnosis of depression, and therefore, these findings cannot be validated.

The role of education in the management of OED

Educational support through delivery of reliable information and individual counselling is necessary to meet the IN, reducing anxiety, and improving satisfaction across patients with OPMDs (Lin et al., 2015) and OED. Also, this can be performed by promoting public knowledge and awareness about the importance of regular dental examination and its role in early detection of OPMDs (de Nooijer et al., 2001, Allen et al., 2015). Additionally, delivering information through a patient information leaflet (PIL) could improve patient knowledge, reduce distress, and motivate them toward oral health screening for oral cancer (Boundouki et al., 2004) but further assessment is required to validate these findings in the OED population.

Informational needs (IN)

The disclosure of information is one of the key elements in the management of patients with oral epithelial dysplasia (OED). Lack of knowledge (Brouha et al., 2005, Scott et al., 2006, Pati et al., 2013, Renzi et al., 2015, Lee et al., 2016) and psychological variables (Panzarella et al., 2014) were among the significant factors linked to delayed diagnosis of oral cancer (OC). In contrast, providing educational support to these patients by delivery of tailored information could perhaps promote their informed choices, actively shared decision-making, higher self-control and autonomy, leading to favourable treatment outcomes. Also, this could improve their experience and coping strategies and concordance toward medical management in addition to reduce the anxiety and stress, improved overall quality of life (QOL), and focus the health care services (Ankem, 2015, Christalle et al., 2019, Pian et al., 2020).

Before exploring the IN, it is important to define the difference between information and knowledge. Information refers to organised data that is externally acquired, whereas knowledge implies the perception, processing, and synthesis of information already obtained (Greer et al., 2013). The trio of informational demand, seeking and needs are considered *"information behaviour",* defined by Wilson (2000) as *"the totality of human behavior in relation to sources and channels of information, including both active and passive information seeking, and information use".* As a broad term, IN is defined as *"a state or process started when one perceives that there is a gap between the information and knowledge available to solve a problem and the actual solution of the problem"*, (Miranda et al., 2007). In contrast, Ormandy has defined the patient's IN as *"recognition that their knowledge is inadequate to satisfy a goal, within the context/situation that they find themselves at a specific point in the time" (*Ormandy, 2011*)*.

The objectives of research on patient's IN

The research on the impact of IN mainly focuses on:

1. *Improving the patient's experience and coping strategies:* informed patients are expected to experience less uncertainty that could enhance their satisfaction, coping strategies, and treatment outcomes including recovery and functioning (Feldman-Stewart et al., 2000, Neumann et al., 2011, Ormandy, 2011, Gillespie et al., 2016). Also, providing suitable information is important to emphasise the partnership in the clinical decision, awareness, familiarity with illness experience, and stability overtime and retention of information (Mesters et al., 2001, Semple et al., 2002). Both the healthcare policy makers and professionals must challenge the patient's passive role in the clinical decision-making process to increase the self-control and autonomy (Pinquart et al., 2004).

2. *Improving the patient's concordance and attitude toward medical management:* among different models of the doctor-patient relationship, the informative model describes that doctors are information providers, and patients are given a choice to select their preference (Emanuel et al., 1992). Health care professionals (HCPs) need to review the individual IN regularly during the disease journey as to ensure meeting these needs accurately, to improve the perception toward the quality of care, and to provide an evidence-based healthcare service (Larson et al., 1996, Davis et al., 1999, Jenkins et al., 2001, Jo et al., 2019). Also, the engagement in decision-making could also reduce the possibility of preventable disease (Gruman et al., 2010, Ormandy, 2011).

3. *Limiting the disease-related anxiety and stress:* multiple studies showed that unmet IN with chronic disease were correlated with increased fear and depression, and reduced satisfaction (Mesters et al., 2001, van der Meulen et al., 2013, Lin et al., 2015, Pieper et al., 2015). Indeed, the anxiety levels are found to affect the personal need for information, ability to absorb and recall the given information (Chen et al., 2009, Brockbank et al., 2015). Interestingly, information provision could, in turn, stimulate the anxiety despite the desire to know the potential complications (Harland et al., 2008, Waldron et al., 2011). Hence, providing the tailored information by obtaining the *'patient's first-hand knowledge'* described by Gerhardt (1990) is necessary to evaluate the psychological impact of the disease and possibly limiting the anxiety stimulated by the informational provision or '*misinformation'*.

4. *Improving the overall QOL:* the ability to meet the patient’s IN and to deliver essential information by HCP are significant determinants of the perception of the quality of care and QOL (Larson et al., 1996). Hence, the QOL could be promoted through strategic healthcare patient-professional interactions, particularly in vulnerable individuals (Smith et al., 2015). This is becoming more notable among those affected by chronic disorders and requires more information due to various encounters on their physical, social, and financial well-being (Fautrel et al., 2005, D'Souza et al., 2013, Mooney et al., 2014). Identifying the patient’s IN would be helpful to address the needed interventions for better QOL (Hsieh et al., 2018).

5. *Focusing the healthcare services on the patient’s needs and preferences and to reduce the healthcare expenditure:* the tailored-communication model should be considered especially in severe illnesses due to various health status, preferences, and needs among different individuals (Rodin et al., 2009, van der Meulen et al., 2013). Aside from improving the quality of care, this could focus the healthcare services and improve the professional-patient communication leading to better utilisation of healthcare resources and expenditure (Luker et al., 1995, Semple et al., 2002, Gruman et al., 2010, Bertakis et al., 2011, Ormandy, 2011, Cosgrove et al., 2013, Ndosi et al., 2015, Okunrintemi et al., 2017).

The role of information provision and locus of control in patients with OED

Since the 1970s, oral cancer (OC) incidence rate increased by 92% in the UK that counted for thirty-one cases per day (Cancer Research UK, 2017). The fear of recalling unnecessary anxiety was one of the barriers of dentist-patient discussions about oral cancer (Awojobi et al., 2015) which may delay the diagnosis of OED and OC. Providing reliable information to dental patients could optimise the perception of their oral symptoms, treatment outcomes and informed choices (Ali et al., 2014). Anecdotally, it could also improve the early detection and prognosis of OED or OC by early symptoms interpretation. This was illustrated by the locus of control (LOC) theory which is constituted by two loci. The internal LOC reflects the individual belief in self-control over his/her health while external LOC demonstrates the belief in health control or influence by factors that cannot be controlled by the individual (Rotter, 1966, Wallston et al., 1978, Syx, 2008).

Higher control over health outcomes is likely to be found among those who have their beliefs driven by the internal LOC (Harkapaa et al., 1991, Syx, 2008, Trento et al., 2008). The research showed that higher satisfaction is correlated with the amount of information provided by their doctors (Kenny, 1995). Given that physicians are usually spending less time for health education (Stirling et al., 2001), assessing the IN could promote the efficiency of the educational process during clinical consultations and perhaps increasing the patient’s satisfaction.

Instruments specifically used in oral epithelial dysplasia (OED)

The identified IN instruments were assessed for content and impact in chapter two. There is no available instrument of use to evaluate the IN of patients with OED. Developing and validating an OED-specific IN instrument could contribute to a better understanding of the individual perspectives toward their disease. Education and individual counselling are necessary to meet the IN for these patients (Lin et al., 2015), however, these perhaps cannot be effectively achieved due to the lack of specific and clinically applicable IN instrument for OED.

KNOWLEDGE GAP AND OBJECTIVES OF THE RESEARCH

A substantial body of literature has highlighted the importance of patient education in shared-decision making and management of chronic and cancer-linked disease such as perhaps oral epithelial dysplasia (OED). The current focus of informational needs (IN) has however been upon non-oral cancer and precancerous conditions. There remain no detailed studies of what information is (and how relevant it is) presently available for patients with OED or indeed what information such patient may wish. Also, assessing the level of agreement between health information provided by clinicians and this needed by patients is frequently overlooked. Also, the evidence is yet lacking as toward the prevalence and severity of anxiety and depression, dental anxiety and oral health-related quality of life among individuals with OED.

Primary Objectives

- To evaluate the content, quality, readability, understandability and actionability of the current patient-oriented online information of OED (chapter 1).
- To assess the content and impact of the present generic and specific information needs instruments (chapter 2).
- To develop and evaluate the psychometric properties (validity and reliability) of new specific information needs instrument on OED (chapter 3).
- To develop and assess a patient information leaflet (PIL) for OED using the data generated by responses to ODIN-Q in the 1st phase of the study (chapter 6).

Secondary Objectives

- To investigate the correlations between the patients' informational needs and preferences for active participation in own health care decisions, psychological variables (e.g. anxiety and depression), oral health-related quality of life and dental anxiety (chapters 3 and 5).
- To investigate the agreement between the clinicians' and patients' views on the informational needs concerning OED (chapter 4).

A summary of the project activities and phases is shown in Figure 3.

Pre-study activities

- Review the current literature with regard to oral epithelial dysplasia and information needs.
- Assess the web-based information of oral epithelial dysplasia and precancer of the mouth.
- Identify and assess the content and impact of existing generic and specific information needs insturments.
- Generate a list of items from the literature review followed by adaption of IN instrument with good psychometric properties.

Study phase 1

- Develop and validate of the information needs questionnaire for oral epithelial dysplasia (ODIN-Q).
- Define the information needs of oral epithelial dysplasia.
- Define who at higher risk of having unmet information .
- Evaluate the preference for active involvement in the decision-making and self-care, hospital anxiety and depression and dental anxiety and oral health-related quality of life using valid and reliable instruments.

Study phase 2

- Develop and assess a patient information leaflet (PIL) about oral epithelial dysplasia.

Figure 3 A summary of the project activities.

CHAPTER I. WEB-BASED INFORMATION ON ORAL EPITHELIAL DYSPLASIA AND PRECANCER OF THE MOUTH – QUALITY, READABILITY, AND UNDERSTANDABILITY

1.1. Introduction

In 2016, the estimated Internet penetration was at 46% and 92% of the world and UK populations, respectively (InternetLiveStats.com, 2017). A US population-based survey showed that around 80% of the web users have searched for online health information (OHI) in the previous year to find information about a medical condition, treatment options, medications, and other topics related to lifestyle (Fox et al., 2013). Concerns exist regarding access to online information and also the quality of web-based health information which refers to how reliable, accurate, trustworthy, current (Magunacelaya et al., 2011), and readable the information is. In addition, there may be concerns regarding the subjectivity of commercial bias (Dy et al., 2012a), whether the content is peer-reviewed (Sacchi et al., 2015), and compliance with rules and regulations (Nichols et al., 2011).

To make the most of their OHI patients require an acceptable level of health literacy. Health literacy empowers individuals by providing the cognitive and social skills needed to *'gain access to, understand and use information in ways which promote and maintain good health'* (Nutbeam, 1998). Those with poor health literacy are believed to have a reduced awareness of their disease process and management as well as a limited appreciation of the way health system work. This makes this group at greater risk of poor health, lower quality of life, and higher mortality than those with good or high health literacy (Davis et al., 2002, Merriman et al., 2002, McInnes et al., 2011). It is thought that health literacy is associated with general literacy, a term which includes the ability of a person to read, write, speak and problem solve (Office of Disease Prevention and Health Promotion, 2015). Therefore, a key element of general literacy and in turn health literacy is the readability of the text material. Current evidence indicates that the readability scores of various web-based health information are higher than recommended reading levels (Walsh et al., 2008, Vives et al., 2009, Sanghvi et al., 2012, AlKhalili et al., 2015, Roberts et al., 2016, Park et al., 2017), thus making the currently available potentially incomprehensible and unusable. Other central paradigms for health literacy are understandability which is described as the ability to ‘process’ and ‘explain’ health information, and actionability which indicates recognizing the needed actions based on the presented information (Shoemaker et al., 2014, Vishnevetsky et al., 2018).

There is limited knowledge about the patient-oriented web content with respect to OED. The use of validated assessment instruments could ease the identification of search engines and websites with relevant content, higher quality, readable, understandable, and actionable written health information. The aim of this study is thus to evaluate the content, quality, readability, and comprehension (understandability and actionability) of web-based information on OED.

1.2. Methods

1.2.1. Search strategy

Web searches for the terms ‘oral dysplasia’, ‘treatment of oral dysplasia’, and ‘treatment of precancer of the mouth’ was carried out between February and May 2017 using the most commonly employed search engines in the UK: Google.com, Yahoo.com, and Bing.com (Alexa.com, 2017). For each term, the first 100 websites per search engine were selected with no refinement.

1.2.2. Exclusion criteria

Links to scientific content (e.g. books or journals), websites that required membership or subscription, websites promoted by search engines, sites that advertise for clinical services or techniques, community-based forums without professional guidance, and websites with only video or audio content were excluded (Jayaratne et al., 2014, McMorrow et al., 2016).

1.2.3. Content assessment

The content of the included web sites was assessed following the categorisation method used by Ni Riordain and McCreary (Ni Riordain et al., 2009), which grouped the websites according to affiliation (commercial, non-profit organisation, governmental, or university/medical centre), specialisation (the site is entirely or partly related to the searched topic), content type (medical facts, clinical trials, human interest stories, and question and answer), and content presentation (image, video, and audio).

1.2.4. Quality assessment

The DISCERN instrument (Charnock, 1998a), Journal of the American Medical Association (JAMA) benchmarks (Silberg et al., 1997), and Health on the Net (HON) seal (Health on the Net Foundation, 2017) were used to evaluate the quality of identified websites. DISCERN is a validated 16-item tool rated by a 5-point scale (5 = complete fulfilment of the quality criterion and 1= none) that aims to ensure making informed choices based on trusted evidence by evaluating the quality of written health information. It includes questions about the reliability of information (items 1-8), treatment choices (items 9-15), and an overall rating question (Figure 1-1).

Question 1: Are the aims clear?

Question 2: Does it achieve its aims?

Question 3: Is it relevant?

Question 4: Is it clear what sources of information were used to compile the publication ?

Question 5: Is it clear when the information used or reported in the publication was produced?

Question 6: Is it balanced and unbiased?

Question 7: Does it provide details of additional sources of support and information?

Question 8: Does it refer to areas of uncertainty?

Question 9: Does it describe how each treatment works?

Question 10: Does it describe the benefits of each treatment?

Question 11: Does it describe the risks of each treatment?

Question 12: Does it describe what would happen if no treatment is used?

Question 13: Does it describe how the treatment choices affect overall quality of life?

Question 14: Is it clear that there may be more than one possible treatment choice?

Question 15: Does it provide support for shared decision-making?

Question 16: The overall quality rating of the publication as a source of information about treatment choices?

Figure 1-1 The DISCERN items (n=16).

JAMA quality benchmarks ensure the accountability of web-based health information by considering the authorship (authors, their affiliations and credentials), attribution (citations, sources, and copyright), disclosure (acknowledging the ownership, sponsorship, advertising, underwriting, funding and support, and possible conflict of interest), and currency (demonstrate the dates and updates) of the given information.

HON is a non-profit foundation that aims to assess the quality and transparency but not the accuracy of web-based health information. HON code of conduct includes eight criteria: authority, complementarity, confidentiality, attribution, justifiability, transparency, financial disclosure, and advertising policy.

1.2.5. Readability assessment

The readability, described as *'the reading comprehension level a person must have to understand written materials'* (Albright et al., 1996), was assessed using an online tool (https://readable.io) considering two readability formulae: Flesch Reading Ease Score (FRES) (Flesch, 1948) and Flesch-Kincaid Grade Level (FKGL) (Kincaid et al., 1975). FRES assesses the readability on a 0-100 scale (0=hardest and 100=easiest), while FKGL estimates the number of years of education in the US needed to understand a passage of written material (Table 1-1). There are no available readability guidelines of the patient-related health information in the UK (Fitzsimmons et al., 2010). Therefore, an approach that considers a range of difficulty as easy (4th, 5th, and 6th grade), average difficulty (7th, 8th and 9th grade), and difficult (10th grade and above) was followed (U.S. Department of Health and Human Services, 2010).

Table 1-1 The formulae of readability indices.

Index	Formula
Flesch Reading Ease Score	206.835 – (1.015 × Average number of words per sentence) – (84.6 × Average number of syllables per word)
Flesch-Kinacid Grade Level	(0.39 × Average number of words per sentence) + (11.8 × Average number of syllables per word) – 15.59

Adapted from: ayaratne, Y.S., Anderson, N.K. and Zwahlen, R.A. 2014. Readability of websites containing information on dental implants. Clin Oral Implants Res 25(12) 1319-1324.

1.2.6. Understandability assessment

The Patient Education Material Assessment Tool (PEMAT) was used to measure the *‘understandability’* and *actionability’* of printed and audio-visual health information (PEMAT-P and PEMAT-AV, respectively) (Shoemaker et al., 2014). PEMAT-P provides numerical scores of the 24 items which are rated, based on correspondence with an item, by 3-point scale (Disagree=0, Agree=1, or N/A) (Figure 1.2).

A summary of all assessment methods is shown on Table 1-2.

Item 1: The material makes its purpose completely evident.

Item 2: The material does not include information or content that distracts from its purpose.

Item 3: The material uses common, everyday language.

Item 4: Medical terms are used only to familiarize audience with the terms. When used, medical terms are defined.

Item 5: The material uses the active voice.

Item 6: Numbers appearing in the material are clear and easy to understand.

Item 7: The material does not expect the user to perform calculations.

Item 8: The material breaks or “chunks” information into short sections.

Item 9: The material’s sections have informative headers.

Item 10: The material presents information in a logical sequence.

Item 11: The material provides a summary.

Item 12: The material uses visual cues to draw attention to key points.

Item 13: The material uses visual aids whenever they could make content more easily understood.

Item 14: The material’s visual aids reinforce rather than distract from the content.

Item 15: The material’s visual aids have clear titles or captions.

Item 16: The material uses illustrations and photographs that are clear and uncluttered.

Item 17: The material uses simple tables with short and clear row and column headings.

Item 18: The material clearly identifies at least one action the user can take.

Item 19: The material addresses the user directly when describing actions.

Item 20: The material breaks down any action into manageable, explicit steps.

Item 21: The material provides a tangible tool whenever it could help the user take action.

Item 22: The material provides simple instructions or examples of how to perform calculations.

Item 23: The material explains how to use the charts, graphs, tables, or diagrams to take actions.

Item 24: The material uses visual aids whenever they could make it easier to act on the instructions.

Figure 1-2 PEMAT-P items.

Table 1-2 Summary of the assessment methods for web-based information

Type of assessment	Assessment method
Evaluation of information type and content	Following the website categorisation method used by Ni Riordain and McCreary (2009): 1. Affiliation: commercial, non-profit organisation, governmental, or university/medical centre. 2. Specialisation: the sites are either entirely/partly related to the searched topic. 3. Content type: medical facts, clinical trials, personal stories, and question and answer. 4. Content presentation: image, video, and audio
Assessment of information quality	1. DISCERN instrument (Charnock, 1998a). This tool aims to evaluate the quality of written information regarding treatment choices for a health condition. It includes 15 questions (Figure 1-3) rated by 5-point scale (5 = complete fulfilment of the quality criterion and 1= none). 2. Journal of the American Medical Association (JAMA) quality benchmarks for online medical information (Silberg et al., 1997). The following benchmarks aim to ensure the accountability of web information: *i. Authorship* *ii. Attribution* *iii. Disclosure* *iv. Currency* 3. Health on the Net (HON) seal (Health on the Net Foundation, 2017). This non-profit foundation primarily aims to assess the quality and transparency but not the accuracy of web-based health information. HON code of conduct includes 8 criteria: *authority, complementarity, confidentiality, attribution, justifiability, transparency, financial disclosure, and advertising policy.*
Assessment of information readability	The readability is assessed by copying the text of initial page of identified websites and paste it on a web automated tool (https://readable.io) using the following readability formulas (Table 6): 1. Flesch Reading Ease Score (FRES): measuring the readability on 0 to 100 scale (0=hardest to read while 100 is the easiest) (Flesch, 1948).

	2. Flesch-Kinacid Grade Level (FKGL): this formula estimates the number of years of education in the US needed to understand a passage of written material (Kincaid et al., 1975, Schwarm et al., 2005, McInnes et al., 2011).
Assessment of information understandability and actionability	The ability to understand and act on the presented health information was assessed by the 24-item Patient Education Material Assessment Tool for printed information (PEMAT-P) which is rated by 3-point scale (Disagree, Agree, or Not Applicable) (Shoemaker et al., 2014, Beaunoyer et al., 2017). Percentages being calculated using this formula [(the total sum score/the number of items) × (100)] for each domain (i.e. understandability and actionability). A higher percentage reflects higher chance of meeting the purposes of these domains of PEMAT-P.

1.2.7. Data analysis and representation

The data was collected using a study specific proforma and recorded in Microsoft Excel to facilitate descriptive statistics. The representation of variables was performed by IBM SPSS (version 22.0). To ensure the intra-rater agreement of DISCERN, one of the identified websites was randomly selected and re-assessed by the same investigator (AA), two months after the initial evaluation and the intraclass correlation coefficient (ICC) was determined (McMorrow et al., 2016). Also, the ICC was calculated to ascertain the level of agreement on DISCERN scores between two investigators (AA and RNR) using one randomly selected site. Ethical approval was not required for this study.

1.2.8. Ethical Consideration

Ethical approval was not required for this study.

1.3. Results

1.3.1. The content and categorisation of all analysed websites

Only 80 out of 900 websites met the inclusion criteria however 36 sites were considered for the summary evaluation after eliminating the duplicates. The screening results for all searches are summarised in Figure 1-3.

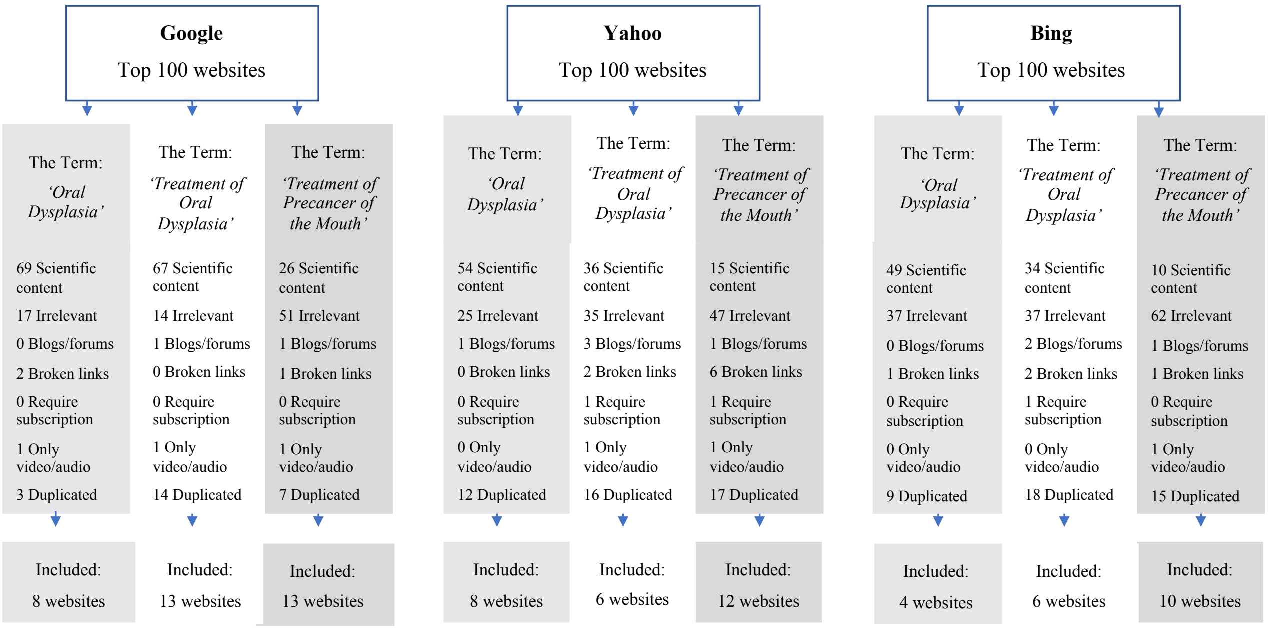


Figure 1-3 Screening results for all searches.

For all searches, Google yielded the highest relevant content to patients, less non-operating and duplicating links than both of Yahoo! and Bing. Regarding search terms, "treatment of precancer of the mouth" generated the most relevant websites to patients with all search engines (n=35) followed by 'treatment of oral dysplasia' (n=23), and 'oral dysplasia' (n=20).

Regarding ownership of all identified websites, most were of North American origin (US or Canada) with a few other websites from UK and East Asia. 12 of the websites belonged to commercial establishments (33%), 12 were non-profit organisations (33%), 11 were university/medical centres (30%), and one website was governmental agency (2%). Most websites were not limited to but included details about OED (83%). The medical facts were the most used content type (87.5%) followed by question and answer (47%) in addition to clinical trials and human-interest stories (5%). Also, clinical and pathological images were used in 19 websites (52%) while a video and/or audio were limited to one site for each (2.70%) (Table 1-3).

Table 1-3 Summary of categorisation of the analysed websites according to affiliation, specialisation, and content type (n=36).

Category	**Criteria**	**Number of websites (%)**
Affiliation	Commercial	12 (33.33%)
	Non-profit organisation	12 (33.33%)
	Governmental	1 (2.77%)
	University/medical centre	11 (30.50%)
Specialisation	Site is entirely related to oral precancer	6 (16.66%)
	Site is partially related to oral precancer	30 (83.33%)
Content type	Medical facts	30 (83.33%)
	Clinical trials	2 (5.55%)
	Human interest stories	2 (5.55%)
	Question and answer	17 (47.22%)
Content presentation	Image	19 (52.77%)
	Video	1 (2.77%)
	Audio	1 (2.77%)

1.3.2. The quality assessment (DISCERN, JAMA benchmark, and HON seal) for all analysed websites

DISCERN

The DISCERN scores for the 36 identified websites are summarised in Table 1-4. The overall rating (question 16) ranged from 1 to 4 with a mean score of 2.24 (±0.90) and median of 2. The highest mean scores were associated with relevance (3.89) and explicit aims (3.56). While the questions which scored lower than 2 out of 5 include explicit sources (Q4), risks of treatment (Q11), effects of treatment choices on quality of life (Q13), and shared decision (Q15). The intra and inter-rater agreements of DISCERN were at 0.789, which demonstrate a good reliability (Weir, 2005, Koo et al., 2016).

Table 1-4 The mean and median DISCERN scores of the 36 selected websites.

Domain	DISCERN question	Mean score (Std. Deviation)	Median score
Reliability	Q1. Explicit aims	3.56 (±0.80)	3.00
	Q2. Attainment of aims	3.19 (±1.16)	3.00
	Q3. Relevance	3.89 (±0.91)	4.00
	Q4. Explicit sources	1.86 (±1.22)	1.00
	Q5. Explicit date	2.31 (±1.30)	2.00
	Q6. Balanced and unbiased	2.97 (±1.02)	3.00
	Q7. Additional sources	2.47 (±1.46)	2.00
	Q8. Areas of uncertainty	3.08 (±1.18)	3.00
Treatment options	Q9. How treatment works	2.25 (±1.15)	2.00
	Q10. Benefits of treatment	2.14 (±1.07)	2.00
	Q11. Risk of treatment	1.97 (±1.08)	2.00
	Q12. Effects of no treatment	2.22 (±1.09)	2.00
	Q13. Effects on quality of life	1.92 (±1.10)	2.00

	Q14. All alternatives described	3.00 (±1.58)	3.50
	Q15. Shared decision	1.86 (±1.17)	1.00
Overall rating		2.42 (±0.90)	2.00

JAMA benchmark

The *disclosure* was the highest met benchmark (71%). In contrast, the *authorship*, *attribution*, and *currency* were not adequately achieved (27%, 27%, and 35% respectively) (Figure 1-4). Four benchmarks were met in 2 websites (6%), three benchmarks met in 5 websites (14%), two benchmarks met in 11 websites (31%), one benchmark was met in 14 websites (39%), and no benchmark was found in 4 websites (10%) (Figure 1-5).

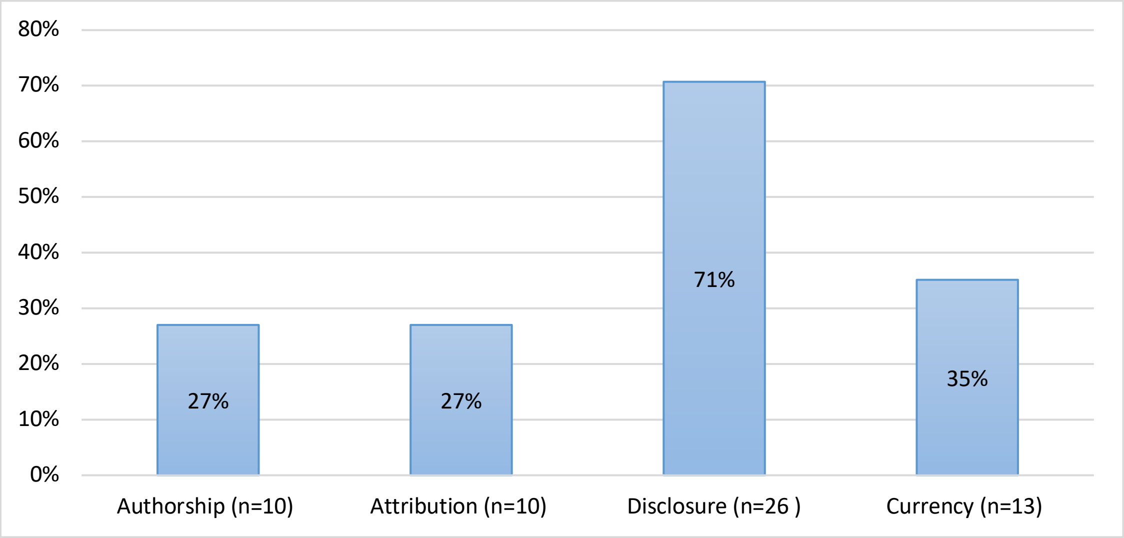


Figure 1-4 The JAMA benchmarks achieved by number and percentage of the 36 identified websites.

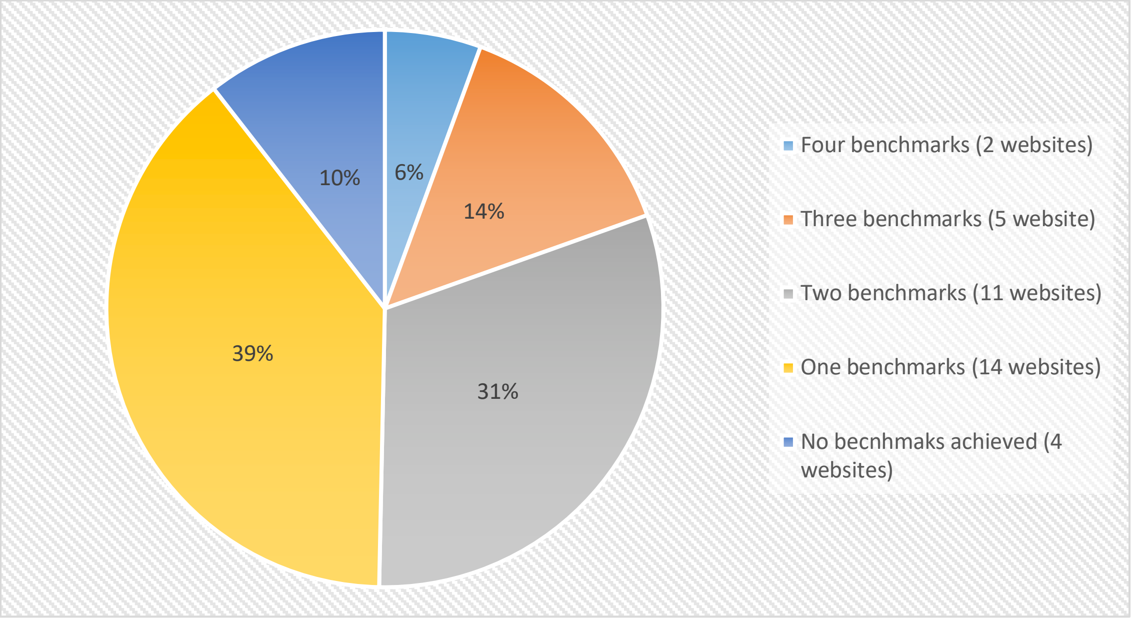


Figure 1-5 The number of JAMA benchmarks achieved by all websites (n=36).

HON seal

Only ten of the identified websites (27%) displayed the HON seal.

1.3.3. Readability assessment

The overall readability scores and grade levels widely varied across the examined websites (Table 1-5). Using the FRES formula, the range of scores was between 18.1 and 71.9 with a mean and median of 47.65 (±13.63) and 47.50, respectively. An analysis with the FKGL showed a range of grade levels from 5th grade to university level (14th grade) with mean and median around 10th grade. Regarding easiness of reading, 22 out of 36 websites were considered as difficult to read (55%), 7 were fairly difficult (19%), 6 were standard (16%), 2 were fairly easy (5%), and one website was very difficult to read (2%) (Figure 1-6).

Table 1-5 The mean, standard deviation, median, maximum and minimum readability score and level (n=36).

	Mean (Std. Deviation)	Median	Maximum	Minimum
Flesch Reading Ease Score (FRES)	47.65 (±13.63)	47.500	71.9	18.1
Flesch-Kincaid Grade Level (FKGL)	9.87 (±2.30)	10.150	14.6	5.4

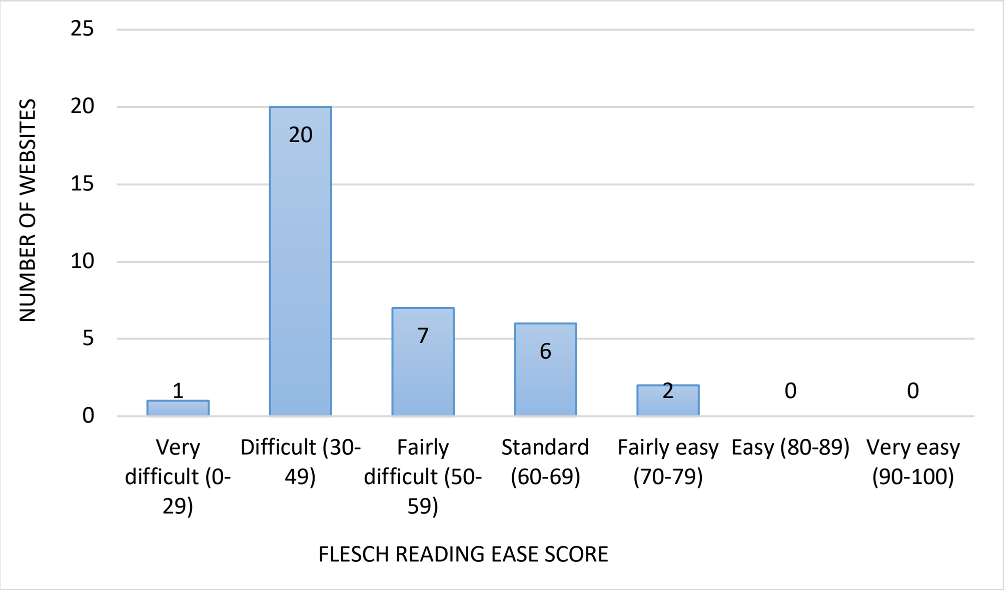


Figure 1-6 The categorisation of the 36 selected websites based on the easiness of reading.

1.3.4. Understandability and actionability assessments

The mean and median PEMAT-P understandability scores were 62.67 (±22.92) and 68 on a 0-100 scale, with scores spreaded between 13 and 94 (Figure 1.7). In contrast, the actionability scores were notably less with mean and median scores of 42.33 (±24.66) and 46 and a range of scores between zero to 83. The total mean and median scores for PEMAT-P were 52.5 and 57 (Table 1-6).

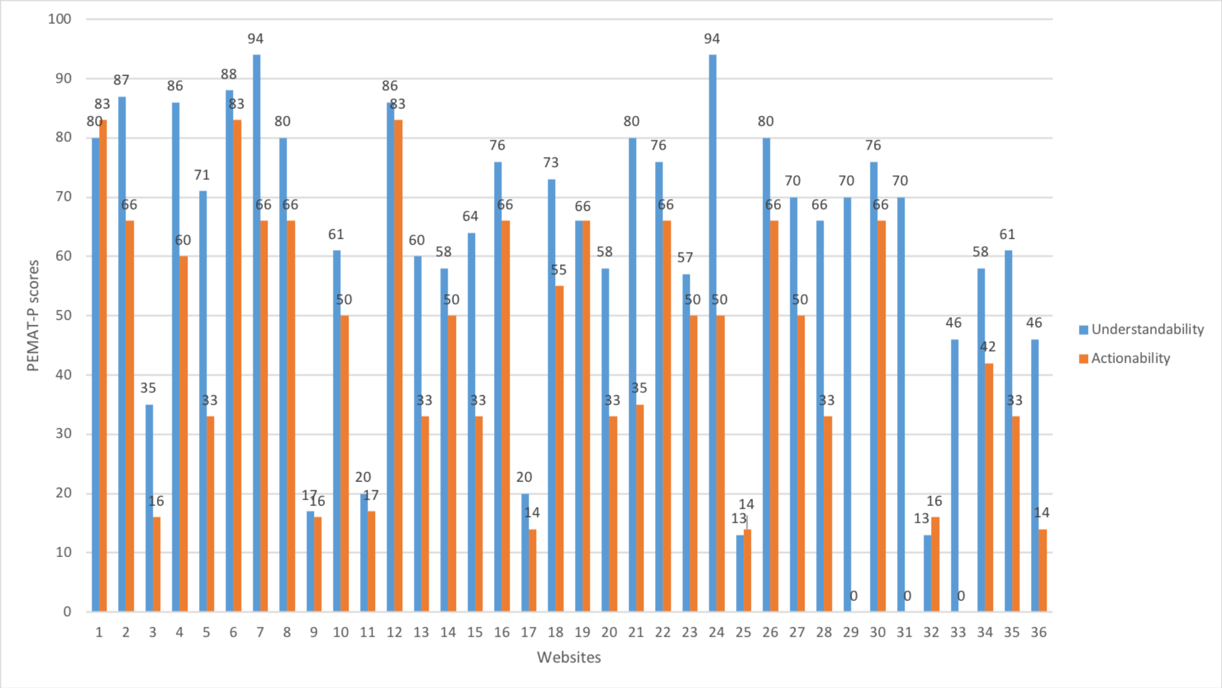


Figure 1-7 PEMAT-P scores of the analysed websites (n=36).

Table 1-6 The mean, standard deviation, median, maximum and minimum of PEMAT-P scores (n=36).

	Mean (Std. Deviation)	Median	Maximum	Minimum
Understandability	62.67 (±22.97)	68.00	94	13
Actionability	42.33 (±24.66)	46.00	83	0

1.4. Discussion

Individuals are motivated to seek health information online in an attempt to seek reassurance, to find alternative opinions on medical interventions and to better comprehend information delivered in the clinical setting (Powell et al., 2011). This information-seeking behaviour can aid the ‘shared-decision making’ model being promoted in healthcare interactions (Powell et al., 2011). For example, those affected by OPMDs and other potentially malignant conditions frequently use the Internet to obtain information about their condition and treatment options in spite of the potential for unaddressed worries that may arise from the information generated (Alcaide-Raya et al., 2010). Although a previous study noted general acceptability of quality of web-based information of OPMDs, no validated assessment tool was used in that study (Alcaide-Raya et al., 2010). Also, none of the terms searched in the current analysis were considered in the earlier study.

The content of patient-oriented web information related to OED

Nine searches were performed in the current study using different terms and search engines to ensure a thorough web analysis of OED. The results indicate that there is a scarcity of patient-oriented web content of OED as only 36 websites of 900 websites were suitable for patients. Other similar studies had a range 50 to 300 websites in their initial assessment (Ni Riordain et al., 2009, Aldairy et al., 2012, Ni Riordain et al., 2014, McMorrow et al., 2016, Wiriyakijja et al., 2016). Only 3 of these websites in this study had content specifically devoted to OED with minimal information content in these 3 OED specific sites.

The quality of patient-oriented web information related to OED

Despite the criticism that DISCERN may not comprehensively assess the web content when compared to JAMA benchmarks, a previous study noted its satisfactory internal consistency and inter-rater reliability (Ademiluyi et al., 2003). The mean of overall rating by DISCERN was at 2.42 out of 5 which is similar to other studies of oral leukoplakia (2.3) (Wiriyakijja et al., 2016) and head and neck cancer (2.55) (Ni Riordain et al., 2009). As with previous studies, questions concerning sources to compile the publication (Ni Riordain et al., 2014) as well as those related to the risks of each treatment, effects of treatment choice on quality of life, and support for shared decision-making (Wiriyakijja et al., 2016) had notably low mean scores. Like the findings of DISCERN, the JAMA benchmarks, authorship, attribution, and currency, were only achieved in around one-third of the identified websites - which is low compared to head and neck cancer (66%, 69%, and 84% respectively) (Ni Riordain et al., 2009), oral leukoplakia (50% of each) (Wiriyakijja et al., 2016) but similar to the findings reported with oral ulcers (27%, 33%, and 61% respectively) (Ni Riordain et al., 2014). Given that a website failing to fulfil a minimum of three of these criteria might be considered as suspicious (Silberg et al., 1997) - 80% of the websites included in this analysis would fall in this category. Due to the lack of JAMA benchmarks achieved the information on the majority of these sites may not be trustworthy and may, therefore, set unrealistic expectations regarding treatment interventions. This could then perhaps adversely influence the patients' ability to make autonomous and informed decisions (Braddock et al., 1999, Stairmand et al., 2015, Wiriyakijja et al., 2016).

Although HON was introduced in 1995, its application is still limited, perhaps due to a lack of awareness of its existence by designers of health information websites. In addition, the certification process can take up to 14 weeks (Health on the Net Foundation, 2017) and thus may serve as a deterrent to usage. This was possibly evident in our study as only 27% of the analysed websites have maintained the HON code seal a rate however that is higher compared to adult orthodontics at 2% (McMorrow et al., 2016), oral ulceration at 7% (Ni Riordain et al., 2014), and oral leukoplakia at 17% (Wiriyakijja et al., 2016). Nonetheless, it is important to note that organisations such as the NHS have developed a more sophisticated quality mark called Information Standard, which was not considered in this study due to its very recent introduction (NHS England, 2017).

The readability of patient-oriented web information related to OED

Both FRES and FKGL indices used in the present analysis measure the readability by using the word and sentence length but with different formulae. The present analyses showed that only users who at or above 10th grade (US schools) might be likely to comprehend the content of the websites. These levels far exceeded those recommended by the American Medical Association (AMA) for written patient education materials which are at 5th to 6th grade levels or even lower in practices attended by individuals with expected lower literacy (Weiss, 2007). Achieving these recommendations is necessary to enable all readers with different literacy levels to comprehend the information and to enhance the informed decisions about their conditions (McMorrow et al., 2016).

The understandability and actionability of patient-oriented web information related to OED

PEMAT is a relatively new tool developed to overcome the limitations of readability formulas such as mathematically calculating the readability grade level of a text (e.g. FKGL) rather than measuring one's level of comprehension (understandability) and ability to act (actionability) after presenting health information (Shoemaker et al., 2014, Vishnevetsky et al., 2018). Although PEMAT has shown good inter-rater reliability for both scales (PEMAT-P and PEMAT-AV) (Zellmer et al., 2015, Vishnevetsky et al., 2018), it has not been used yet in dental research possibly due to its recent development. Having the PEMAT-P understandability and actionability mean scores below 70% (62% and 42%, respectively), the majority of these websites are poorly understandable and actionable (Shoemaker et al., 2014). These findings were similar to those from web-based health information studies on heart failure (56% and 34%) (Cajita et al., 2017) and tonsillectomy (66% and 39%).

The role of information provision in the management of chronic disease such as OED

Living with a chronic and potentially malignant disease such as OED often requires effective health behaviour changes, which necessitate that an individual has an awareness of their disease and is provided with the information and skills necessary to initiate and maintain these behaviour changes (Schwarzer et al., 1995). The most important modifiable risk factors for oral cancer are tobacco, excessive alcohol consumption and the use of betel quid (Warnakulasuriya, 2010). Numerous studies have evaluated the impact of online interventions to change health behaviours, including disease management and tobacco smoking cessation (Strecher, 1999, Portnoy et al., 2008). When considering smoking cessation specifically, online interventions are considered to have the potential to increase cessation rates thereby having a positive influence on a key modifiable risk factor in patients with potentially malignant oral disease.

There is limited knowledge of the psychological impact of oral cancer symptoms upon affected individuals (Noonan, 2014). Individuals with other suspected cancer conditions (e.g. breast, lung, and colorectal structures) reported negatively affected quality of life and high levels of anxiety at the pre-diagnostic phase that can remain despite having a later benign outcome (Brocken et al., 2012, Ndukwe et al., 2012, Brocken et al., 2015). The possible reasons why the diagnosis of OED may cause distress may include the perception of threat to life, experienced symptoms including pain and disability, and treatment and its effects on physical and psychosocial well-being. Thus, providing tailored information for patients with longstanding conditions such as OED must acknowledge their information needs and considering the impact of the illness and its treatment on physical and psychological well-being (Luker et al., 1995, Foster et al., 2015, Kassianos et al., 2016). One evolving method is to acquire these aspects by patient-based information needs assessment scales. There are tools available for various chronic disorders, but none of these is known to be suitable to assess the need for information for OED specifically.

Available information on oral dysplasia at health speciality organisations

Since health professional organisations are regarded as reliable sources for health information to patients and public (Dy et al., 2012a), the relevant societies were searched deliberately and a patient information leaflet of OED found at British Society of Oral Medicine (BSOM) website (BSOM, 2016). This leaflet showed good quality by achieving an overall rating of four out of 5 by DISCERN and obtained three out of four JAMA benchmarks. However, it did not provide information about making informed decisions or what sources of information used to compile the leaflet. Similarly, the information about how the treatment works, its benefits or risks, and its effect on the quality of life are not available or minimal. Also, its FRES score was at 51, which was fairly difficult to read. Another section about premalignant oral lesions, which was included in the analysis of the current study, is presented at the American Academy of Oral Medicine website (AAOM, 2008). This section obtained a good overall rating by DISCERN (4 out of five) and however only 2 out of the four JAMA benchmarks (authorship and disclosure). Its readability level was difficult to read (FRES = 45) which was similar to findings from other studies (Weiss, 2007).

Through partnerships with medical practices and health speciality organisations, clinicians should consider the imperfections addressed by the current study and acknowledge the published literature and continuing professional development events while creating credible and user-friendly written health materials to patients and public (Weiss, 2007, McInnes et al., 2011). Also, there is a need to improve the searching algorithms by Web search engines (Dy et al., 2012a) as to ensure finding reliable information sources if other descriptions of OED are being searched (e.g. oral precancer or oral potential malignant disorders).

Available information on oral dysplasia at Wikipedia

Wikipedia is a freely accessed web-based encyclopaedia that was founded in 2001 (Anderson, 2008). It has been maintained by a non-profit organisation (Wikimedia) who allows around 40 million editors to publish and revise the content of more than 6 billion pages and 300 languages mainly the English (Laurent et al., 2009, Anderson et al., 2016, Wikipedia, 2020). If a health topic or a condition searched on the commonly used search engines, there is more than 70% chance to find Wikipedia pages within the first ten searched pages (Laurent et al., 2009). Nevertheless, only two of the nine performed searches presented the same Wikipedia page about 'leukoplakia' (Appendix 1). The searched terms were 'oral dysplasia' in Yahoo and 'treatment of oral dysplasia' in Google.

When this page was assessed for quality, it presented an overall DISCERN score of 3, which however exceeded the overall mean and median scores of 36 studies (2 and 2.3, respectively). Although, it presented low scores (≤2 out of 4) for *'shared decision'* and relatively low ratings for *'balanced and unbiased', 'benefits of treatment', 'risk of treatment'* and *'effects on quality of life'* items of DISCERN. Similarly, the '*authorship'* and '*disclosure'* JAMA quality benchmarks and the HON seal were not achieved. The content was unlikely to maintain the reader attention due to the challenging readability (11th grade level) and lengthy content of 13 A4-size pages (without references). This was also reflected by very low PEMAT-P understandability and actionability scores (17 and 16 on a 0-100 scale, respectively).

The page was notably written for health care professionals with the international classification of the disease codes and links to scientific publications offered within its content. As health information seekers could search topics within Wikipedia (Brigo et al., 2015, Huisman et al., 2020), the three present terms were also searched on the 30th of July 2020 using the Wikipedia search tool (https://www.wikipedia.org). The term 'treatment of precancer of the mouth' did not yield any relevant results. Whereas those of 'oral dysplasia' and 'treatment of oral dysplasia' yielded the same five potentially related pages within the first 20 pages of each search.

Aside from the previously assessed page on 'leukoplakia', the pages about 'mouth ulcer' (https://en.wikipedia.org/wiki/Mouth_ulcer) did not include any information about OED. In contrast, the three other pages on 'erythroplakia' (https://en.wikipedia.org/wiki/Erythroplakia), 'oral cancer' (https://en.wikipedia.org/wiki/Oral_cancer) and 'oral candidiasis' (https://en.wikipedia.org/wiki/Oral_candidiasis) included minimal OED content under the diagnosis and treatment headings. Similar to the 'leukoplakia' page, the content of these pages did not address the shared decision-making or the effects of treatment on quality of life, and it was difficult to read (between 11th to 13th grades level). Similar concerns remained toward the aspects related to understandability (e.g. including distracting information, using passive voice and complicated visual aids) and actionability (e.g. lack of actionable steps) of these pages.

Wikipedia indicated that 'the page does not exist' for each of the employed terms. Thus, there is a high need to develop a Wikipedia page about OED that is relevant and addressing the existing deficiencies of content related to the decision making, treatment risks and effects on quality of life (Charnock, 1998b). This page may only consider presenting basic and necessary information about OED with links to further information (e.g. other oral premalignant disorders) – as frequently preferred by those who search Wikipedia (Huisman et al., 2020).

Moreover, it is necessary to address the principles related to understandability (e.g. using active, clear, non-distracting and layperson-oriented content, visual aids, informative headings and a summary) and actionability (e.g. actively addressing the reader and presenting further actions and steps) (Shoemaker et al., 2014). Using the objective and valid quality assessment scales as well as those related readability, understandability and actionability of health information may help to reduce the reported limitations of Wikipedia pages including the subjectivity to systemic, selection and gender biases (Wikipedia, 2020). It is also worthwhile if the professional societies, allied to oral medicine, liaise with Wikipedia to revise the existing content on oral mucosal disease including the OPMDs (Heilman et al., 2011, Wicks et al., 2012). Perhaps this could be comparable to the Cochrane-Wikipedia project (https://uk.cochrane.org/uk-wikipedia-project) that aims to improve health information on Wikipedia, or another professional initiative to edit the Wikipedia's skin disease-related content (Hutton et al., 2019).

Patient support groups as a supplementary source of valid and reliable information

Patient support groups can be valuable in patient education by acting a source of informational support, first-hand experience, and positive impact on changing one's attitude toward their an illness that is chronic such as cancer (Helgeson et al., 2000, BSOM, 2016) and precancerous conditions (Sugerman et al., 2002). Further to the advantages of face-to-face support groups, online support groups have been extensively developed for numerous conditions as toward its easy access, overcoming geographical and time restraints, and anonymity (Wright et al., 2003, Bartlett et al., 2011). In dental health care, these groups can provide a supportive atmosphere to share previous experiences and concerns about dental management and motivation to dental visit especially across dentally anxious individuals (Buchanan et al., 2007, Eijkman, 2007). Dental anxiety and fear may act as a barrier from attending regular dental visits (Eijkman, 2007) and therefore such motivation is necessary especially when it comes to reporting the worrying symptoms (e.g. change in appearance or size) of OED to the dental practitioner.

Examples of websites providing support groups that can be suitable for patients with OED in the UK include disease support groups [e.g. Mouth Cancer Foundation (http://mouthcancerfoundation.org) and UK Lichen Planus (https://www.uklp.org.uk)] and alcohol/smoking cessation groups (subjected to availability at the local NHS provider). Despite its advantages over face-to-face support groups (Scott, 1999), concerns remain toward the accuracy of shared information via online support groups as well as the cost of access to the Internet and shortage of professional facilitators (Klemm et al., 1998, Coulson et al., 2007).

The strengths and limitations of the study

Strengths include conducting nine searches of different search engines and terms as well as using more than one assessment tool per criteria (i.e. quality and readability) compared with previous studies that used a single method of each criteria (Aldairy et al., 2012, Dy et al., 2012b, Sacchi et al., 2015). This study showed that a tangible checklist to act on the presented information was unavailable in the majority of sites. Presenting such checklist that includes risk factors of oral cancer alongside information about these conditions may help to raise the awareness and knowledge of malignant changes and thus encourage seeking early professional opinion – if such symptoms are spotted (Scully et al., 2014, Awojobi et al., 2015).

Aside from the limitations of each assessment tool, this study is limited by restricting the search to English websites at a one-time point and considering the initial page of each link. Although 77% of OHI seekers in the US begin the search for information using a search engine, it is important to consider other sources such as medical information websites (e.g. WebMD), social network sites (e.g. Facebook) (Fox et al., 2013) as well as mobile health applications (IMS Institute, 2015).

1.5. Conclusion

The available web-based information on OED has little content specifically relating to OED and is generally of low quality. The readability scores, as shown by FRES and FKGL, are well above the recommended levels for written health materials. Thus at present patients seeking online information on OED are likely to have difficulty in finding and understanding reliable information about such disease and its possible impact upon their life. Further work is required to generate a web-based resource for OED that addresses the shortfalls demonstrated by the current study.

CHAPTER II. HEALTH INFORMATION NEEDS INSTRUMENTS: A CRITICAL ANALYSIS OF THE CONTENT AND BIBLIOMETRIC PROPERTIES

2.1. Introduction

Whilst needs assessment is focused on limiting the existing gaps and to understand the difference between ‘desired state’ versus individual perceived reality, the health needs assessment is defined as *‘a systematic review of the health issues facing a population leading to agreed priorities and resource allocation that will improve health and reduce inequalities’* (Hooper et al., 2002). Also, the assessment scale is best described as *‘a means of identifying, and possibly gauging the extent of, a specific health or care condition such as ability for personal care, mobility, tissue viability, depression, and cognitive impairment’* (UK Department of Health, 2002c) while the assessment tool is *‘a collection of scales, questions and other information, to provide a rounded picture of an individual’s needs and related circumstances’*.

Needs assessment is involving two processes: (1) acquiring information about the individual’s needs and circumstances and (2) making conclusions of the collected information required to meet these needs and tailored care (UK Department of Health, 2002a). Its advantages include measuring the individual’s values with a measuring scale according to significance and subjectively perceived illness experience (Ferrans et al., 2005). It could also demonstrate the priority of needs, identify patients with higher needs, serve as an educational resource for tailored information, and incite the patient’s active participation and self-efficacy (Bonevski et al., 2000, Mooney et al., 2014, Chernyak et al., 2016).

It is not only the matter of what information to offer to patients by healthcare professionals but also how to offer the appropriate information while avoiding information overload and distress (Gillespie et al., 2016, Latorre-Postigo et al., 2017). Information assessment can be performed by a needs-based or satisfaction-based approach that can be used before and after delivering tailored information (Dall'Armi et al., 2013). Numerous instruments can be used for different conditions due to lack of distinction of specific fields of application. Existing reviews on these instruments have principally focused upon instruments related to cancer, of non-clinical cohort or excluding generic instruments that contain a few IN items (Ankem, 2005, Christalle et al., 2019, Pian et al., 2019).

Analysing the publication trends and the highly cited articles on a certain topic was employed to measure the impact of publications on their targeted audiences and possibly show the scientific outreach of an article as well as its author/s and journal (Kulkarni et al., 2009, Bielsa et al., 2016). Such analysis was performed for specific health disciplines [e.g. gastroenterology and hepatology (Azer et al., 2016)], health conditions [e.g. tuberculosis (Shao et al., 2016)] and health care procedures [e.g. liver transplantation (Ozbilgin et al., 2017) and craniofacial distraction (Hashmi et al., 2017)]. None of these studies examined the bibliometrics related to instruments that can be uitlised to assess the patient's IN.

The chapter aims primarily to describe the suitable instruments that can be employed to assess a patient's information needs specifically or include items related to these needs, which field of application and targeted population and which languages and methods used to develop these instruments. Secondarily, analysing the bibliometric indicators, with its limitations (Belter, 2015, Azer et al., 2016), would be useful to quantify the use of a publication on instruments that can measure IN as well as its impact on other publications Thus, the present review may help further work to investigate IN in their intended purpose of use by clinicians during routine clinical care, researchers who may conduct studies on validation, cross-cultural adaptation and psychometric properties of these instruments and health care policymakers who may plan and implement tailored educational interventions for individuals with unmet needs.

2.2. Methods

2.2.1. Search strategy and eligibility

- Searches were conducted following a comprehensive search strategy as used by Tariman et al (2014) to review the information needs priority in patients with cancer by searching medical subject headings needed in the present study such as ‘information needs’ and ‘patient education’ of adult patients and published in the English language using three databases (CINAHL, PubMed, and PsycINFO).
- The following medical subject headings terms were used in combination or solely: information needs, patient needs assessment, health education, patient education, information seeking, patient preferences, assessment scale, patient engagement, questionnaire and/or validation. An asterisk* followed these terms to include different formats (e.g. information or informational) and nouns (e.g. questionnaire or questionnaires). Secondary searches to determine the citations of the identified instruments was undertaken using Scopus

(https://www.scopus.com), which incorporates the highest number of studies in clinical medicine (Li et al., 2010).

- Searches for bibliometric data in Scopus were performed once over two days (20 and 21 August 2019) to ensure the accuracy of the bibliometric findings.

Inclusion criteria

- Studies published in the English language
- Studies that included an instrument/questionnaire to assess patients' IN, preferences or satisfaction.

Exclusion criteria

- Validation studies of a previously developed instrument.
- Studies with no report of instruments (e.g. qualitative research or patients' diaries)
- Studies with no patient-reported instruments (e.g. clinician-based measures).
- Study population that do not include patients (e.g. instead are those of carers or relatives)

2.2.2. Descriptive analysis of instruments

The characteristics of the available instruments were assessed using a modified proforma from the COSMIN checklist for systematic reviews of PROMs (Mokkink et al., 2018a). This proforma includes information about the article (primary author, year of publication, language and country and funding source) and instrument (purpose and methods of development, number of items and response options).

2.2.3. Bibliometric analysis of instruments

The bibliometrics for each study were determined using Scopus as employed in previous similar relevant studies (Azer et al., 2016, Liu et al., 2016, Ramos et al., 2019). The number of citations was identified together with the Field-Weighted Citation Impact (FWCI). The FWCI is the ratio of number of citations for an article compared woth the expected number of citations in similar studies (Purkayastha et al., 2019). The bibliometrics of each journal of publication was determined using the Incite Journal Citation Reports (JCR) of Clarivate (https://jcr.clarivate.com). The 5-year impact factor (IF) for each journal, which is calculated by dividing the citations the journal received over the number of its published studies in the recent five years, was retrieved from the Incite JCR analytical database.

Other analysed variables included first author affiliation (e.g. academic/research, hospital or non-profit organisation), department speciality (e.g. cancer and oncology care, psychology and nursing) and number of studies over 5-year intervals from 1978 to the present time.

2.2.4. Data analysis and representation

Data representation and descriptive analyses were conducted using Microsoft Excel (version 16.26). Ethical approval was not required.

2.3. Results

2.3.1. Available IN instruments

Thirty-six IN instruments were identified in the descriptive and bibliometric analyses (Figure 2-1).

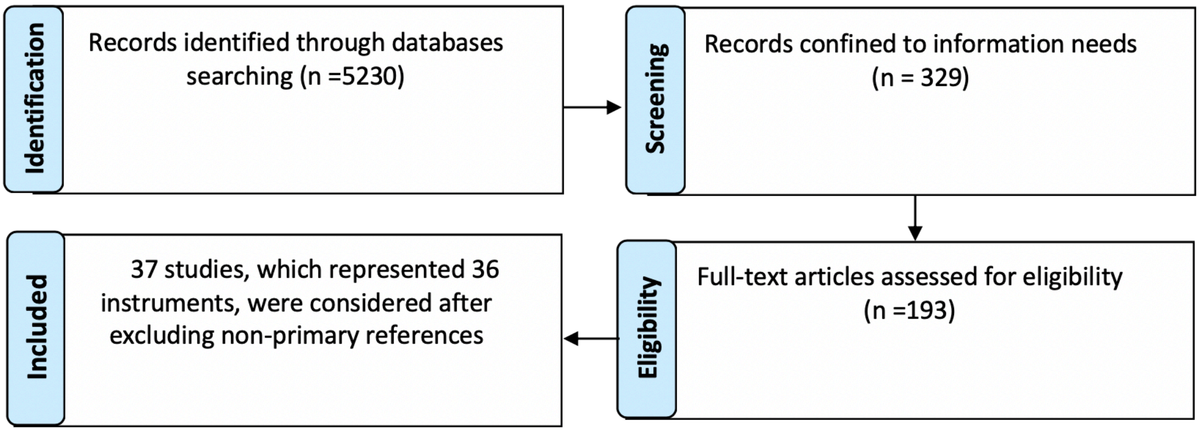


Figure 2-1 The searches flowchart

Based on assessing the patient’s IN, these instruments, were classified to (1) generic instruments which assess different clinical variables (e.g. educational needs) but did include some items related to IN, and (2) specific IN instruments which had been specifically designed to assess a patient’s IN.

Generic (non-specific) instruments

Fourteen generic instruments were identified as having been used to assess IN as well as other variables such as pre-operative anxiety (Moerman et al., 1996), preferences for decision-making and behavioural involvement (Krantz et al., 1980, Ende et al., 1989, Xie et al., 2011) and generic health-related needs (Bonevski et al., 2000, Duggan et al., 2000, Tamburini et al., 2000, Nelson et al., 2004, Osse et al., 2004, Moses et al., 2005, Caljouw et al., 2008, Clinton-McHarg et al., 2012, Cox et al., 2013) (Table 2-1).

71% of the generic instruments (i.e. 10 of 14) were developed in the English language in patient cohorts from the USA (n=5), Australia (3) and the UK (2). Other languages included Dutch (n=3) and Italian (n=1). Nine of these instruments were targeted to a specific cohort of patient such as cancer survivors in childhood (Cox et al., 2013) and adulthood (Clinton-McHarg et al., 2012) as well as other cancer care settings (Bonevski et al., 2000, Tamburini et al., 2000, Thomas et al., 2001, Nelson et al., 2004, Osse et al., 2004, Caljouw et al., 2008). One study was intended to assess individuals in pre-operative surgical care (Caljouw et al., 2008).

Authors often used one or more method to develop these questionnaires with adaptation of a previous instrument/s being the most common approach (Figure 2-2). The average number of items in the generic instruments was 63 (highest=139, lowest=6) rated by multiple response scales. The response option was not reported in one study (Nelson et al., 2004).

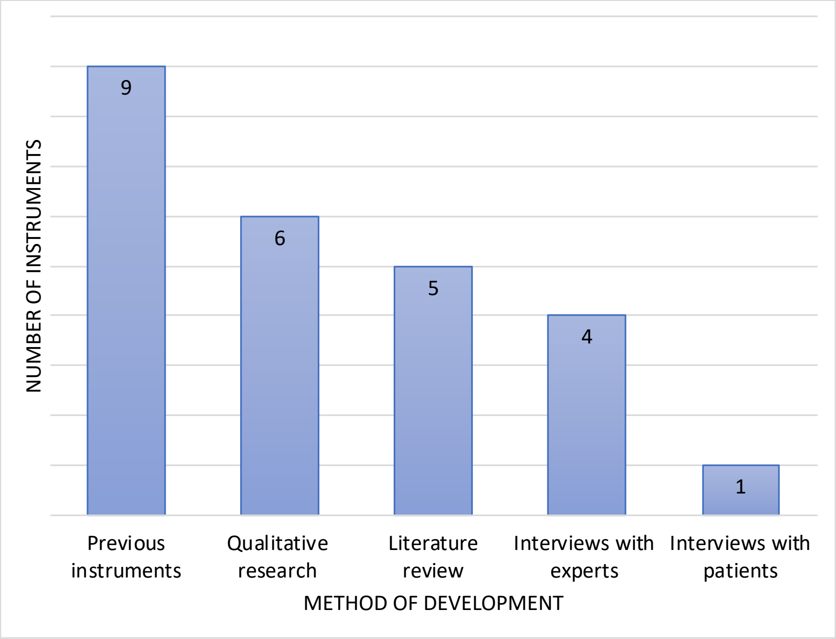


Figure 2-2 The methods to develop the generic instruments (n=14)

Notably, the governmental and non-profit bodies contributed equally to fund these studies (5 studies for each). The four other studies did not declare the source of funding (Krantz et al., 1980, Moerman et al., 1996, Caljouw et al., 2008, Xie et al., 2011).

Table 2-1 The generic instruments (n=14).

Instrument (reference to first article)	**Purpose/ focus**	**Method/s of development**	**Country/ language**	**Number of items**	**Response options**	**Source of funding**
APAIS (Moerman et al., 1996)	Preoperative anxiety and need for information	Previous instrument	Dutch/ Netherlands	2 information-related items out of 6 items	5-point scale (extremely to not at all)	None declared
API (Ende et al., 1989)	Preference for decision-making and information-seek	Interviews with patients and experts	English/ USA	8 information-related items out of 23 items	5-point scale (strongly agree to strongly disagree)	Governmental organisation
IDI (Duggan et al., 2000)	Information and care needs about the prescribed drugs	Interviews with patients	English/ UK	14 information-related items out of 50 items	5-point scale (strongly agree to strongly disagree)	Governmental organisation
HIW (Xie et al., 2011)	Health information needs and decision-making	Previous instruments	English/ USA	40 information-related items out of 80 items	5-point scale (all to none)	None declared
KHOS (Krantz et al., 1980)	The preference for information and behavioural involvement	Literature review and a previous instrument	English/ USA	7 information-related items out of 16 items	2-point scale (yes/no).	None declared
Generic instruments for a specific cohort of patients						
CCSS-NAQ (Cox et al., 2013)	The needs of the childhood cancer survivor	Previous instruments and interviews with patients	English/ USA	29 information-related items out of 135 items	4-response response (from very to not at all)	Non-profit organisation
CNQ-YP (Clinton-McHarg et al., 2012)	The needs of adolescents and young adult cancer survivors	Literature review, interviews with experts and qualitative research	English/ Australia	5 information-related items out of 139 items	5-response response (very high need to no need)	Governmental organisation

HINTS (Nelson et al., 2004)	Cancer care including information-seeking behaviour and health promotion in	Literature review, interviews with experts and previous instruments	English/ USA	6 information-related items out of 35 items	Response options were not reported or could not be determined	Governmental organisation
LPPSq (Caljouw et al., 2008)	Satisfaction with information in perioperative care	A previous instrument and interviews with experts	Dutch/ Netherlands	4 information-related items out of 39 items	5-point scale (completely satisfied to completely dissatisfied)	None declared
NEQ (Tamburini et al., 2000)	Health needs of in-hospital patients with cancer	Qualitative research	Italian/ Italy	5 information-related items out of 23 total items	2-response scale (yes or no)	Non-profit organisations
SLENQ (Moses et al., 2005)	Health needs of patients with systemic lupus erythematous	Literature review, previous instruments and qualitative research	English/ Australia	13 information-related items out of 97 items	5-response scale (high need to no need)	Non-profit organisation
PNI (Thomas et al., 2001)	Psychological needs of patients with cancer and their caregivers	Literature review and qualitative research	English/ UK	5 information-related items out of 48 items	5-response scale (very important to not at all important and very satisfied to not at all satisfied, respectively)	Governmental organisation
PNPC (Osse et al., 2004)	The needs of patients in cancer palliative care	Qualitative research and previous instruments	Dutch/ Netherlands	9 information-related items out of 138 items	2-response scale (yes or no)	Non-profit organisation
(Bonevski et al., 2000)[1]	Health needs in patients with different malignancies	A previous instrument	English/ Australia	10 information-related items out of 60 items	5-response scale (high need to no need)	Non-profit organisations

Specific information needs instruments.

Twenty-two instruments were identified to specifically assess IN for different health disciplines: cancer care (n=15) (Table 2-2), rheumatology (n=3), cardiology (n=1), endocrinology (n=1), pulmonology (n=1) and radiology (n=1) (Table 2-3). Perhaps due to the commonly of cancer and the critical role of patient support during treatment questionnaires have been developed specifically for an organ or a type of cancer including breast (Luker et al., 1995, Bilodeau et al., 1996, Galloway et al., 1997, Chalmers et al., 2001, Mesters et al., 2001, Cohn et al., 2003), blood (Rood et al., 2018), head and neck (Llewellyn et al., 2006, Dall'Armi et al., 2013), cervical (Papadakos et al., 2012) and prostate (Feldman-Stewart et al., 2000, Dale et al., 2004). Another IN-specific instrument was determined to a distinct phase of cancer care (newly diagnosed individuals) (Derdiarian, 1986). Instruments to assess partners and caregivers needs are available but were not with the scope of the present study.

22 (81%) of the specific instruments were available in the English language reflecting the origin of their development (United Kingdom [n=8], Canada [n=6] and the United States [n=5]). Other languages included Dutch (n=2) and German (n=2). In contrast to the most common method of developing generic instruments only 3 out of the 22 IN-specific instruments had used previous instruments and featured to be based upon literature review (n=12) or qualitative research (n=9).

The average number of items in each specific instrument was 48 (highest=144, lowest=12). These items were rated by binary and multiple response scales or a choice to be selected from the list based on a respondent's preference. The response option could not be determined for one study (Cohn et al., 2003). Non-profit organisations provided a fund for half of the 22 studies on IN-specific instruments especially for cancer care (11 out of 15) whereas the governmental bodies came as the second common source of funding.

Table 2-2 The specific information needs instruments for cancer care (n=15).

Instrument (reference to first article)	Purpose/focus	Method/s of development	Original language /country	(Sub)scale (s) (number of items)	Response options	Source of funding
CaPIN (Neumann et al., 2011)	IN of patients with cancer	Interviews with patients	German/ Germany	22 items	2-point scale (yes/no).	Non-profit organisation
DINA (Derdiarian, 1986)	IN of recently diagnosed cancer patients	Literature review	English/ USA	144 items	Presence or absence of information needs	None declared
HaNiQ (Dall'Armi et al., 2013)	IN of patients with the head and neck cancer and their caregivers	Previous instrument	English/ Australia	12 items	3-response scale (yes, no, not sure)	Governmental organisation
HINQ-62 (Rood et al., 2018)	IN of patients with haematological malignancies	Literature review and previous instruments	Dutch/ Netherlands	62 items	5-response scale based on agreement (totally agree-totally disagree to totally agree)	Non-profit organisation
INQ (Luker et al., 1995, Bilodeau et al., 1996)	IN of patients with breast cancer	Literature review	English/ Canada & UK	36 pair of items	An item to be selected from each pair	Governmental and non-profit organisations
ISNQ (Chalmers et al., 2001)	IN of women with a family history of breast cancer	Qualitative research	English/UK	29 items	4-response scale (very important to not very important)	None declared
ISQ (Cassileth et al., 1980)	Preferences for information of patients with cancer	Interviews with patients	English/ USA	A mixture of information preferences, statements' selection and 12 items about information desired	5-response scale for information preferences (no more details than needed to as many details as possible) 3-response scale for information desired (absolutely need this information to do not want this information)	Governmental organisation

SCIP (Llewellyn et al., 2006)	Satisfaction toward treatment-related information in patients with head and neck cancer	Literature review and previous instrument	English/ UK	21 items	4-response scale (too much to none wanted) and 5-response scale (very satisfied to very dissatisfied)	Non-profit organisation
TINQ-BC (Galloway et al., 1997)	IN of women with breast cancer	Literature and interviews with experts	English/ Canada	51 items	5-response scale (extremely important to not important)	Non-profit and commercial organisations
PINQ (Mesters et al., 2001)	IN of patients with Hodgkin's disease and breast cancer	Literature review and qualitative research	Dutch/ Netherlands	17 items	4-response scale (high need to no need)	Non-profit organisation
(Cohn et al., 2003)[1]	IN of women with hereditary early-onset breast cancer	Literature review and interviews with experts	English/ USA	Number of items was not reported or could not be determined	Response options were not reported or could not be determined	Non-profit organisation
(Dale et al., 2004)[1]	IN of patients with prostate cancer	Literature review, qualitative research and interviews with patients	English/ UK	20 items	4-response response for importance (very important to completely unimportant) and amount of information (too much to no information at all)	Non-profit organisations
(Feldman-Stewart et al., 2000)[1]	IN of patients with early-stage prostate cancer	Interviews with patients and experts	English/ Canada	93 items	4-response scale (essential to avoid)	None declared
(Lo et al., 2017)[1]	IN of Women with Ductal Carcinoma in Situ	Qualitative research	English/ Canada	117 items	5-response scale (essential to avoid)	Governmental and non-profit organisations
(Papadakos et al., 2012)[1]	IN of gynaecologic cancer survivors	Literature review	English/ Canada	42 items	5-response scale (very important to not important)	None declared

[1] No instrument abbreviation/name available from the authors.

Abbreviations: IN, information needs; **CaPIN**, Cancer Patients Information Needs; **DINA**, Derdiarian Informational Needs Assessment; **HaNiQ**, Head and Neck Information Needs Questionnaire; **HINQ-62**, Hematology Information Needs Questionnaire; **INQ**, Information Needs Questionnaire; **ISNQ**, Information and Support Needs Questionnaire; **ISQ**, Information Styles Questionnaire; **SCIP**, Satisfaction with Cancer Information Profile**;** **TINQ-BC**, Toronto Informational Needs Questionnaires on Breast Cancer; **PINQ**, Patient Informational Need Questionnaire.

Table 2-3 The specific information needs instruments (n=7)

Instrument (reference to first article)	Purpose/focus	Method/s of development	Original language /country	Number of items)	Response options	Source of funding
Cardiology						
INCR (de Melo Ghisi et al., 2013)	IN of patients in cardiac rehabilitation	Literature review	English/ Canada	60 items	5-point scale (very important to really not important)	None declared
Endocrinology						
(Chernyak et al., 2016)[1]	IN of patients with diabetes mellitus	Literature review and qualitative research	German/ Germany	12 topics and 12 items	Three topics to be selected and 4-response scale (very well to not informed at all), respectively	Governmental organisation
Pulmonology						
LINQ (Hyland et al., 2006)	IN of patients with COPD	Qualitative research	English/ UK	16 items	Multiple-response scale (yes and no or 4-choice answer)	Commercial organisation
Radiology						
(Nekhlyudov et al., 2005)[1]	IN for involvement of women before their first mammogram screening	Qualitative research	English/ USA	10 items	5-point scale (extremely important to not at important)	Governmental organisation
Rheumatology						
ENAT (Hardware et al., 2004)	Information needs of patients with rheumatoid arthritis and other rheumatic conditions	Literature review and qualitative research	English/ UK	39 items	5- response scale (extremely important to not at all)	Governmental organisation
VINQ (Mooney et al., 2014)	IN of patients with ANCA-associated vasculitis	Qualitative research	English/ UK & USA	33 items	5-response scale (extremely important to not important)	Governmental and non-profit organisations
(Cooksey et al., 2012)[1]	IN of patients with ankylosing spondylitis	Interviews with experts	English/ UK	Number of items was not reported or could not be determined	4-response scale (response options were not reported or could not be determined)	Non-profit organisation

[1] No instrument abbreviation/name available from the authors.

Abbreviations: IN, information needs; **INCR**, Information Needs in Cardiac Rehabilitation; **LINQ,** The Lung Information Needs Questionnaire; **ENAT**, Educational Needs Assessment Tool; **VINQ**, Vasculitis Informational Needs Questionnaire.

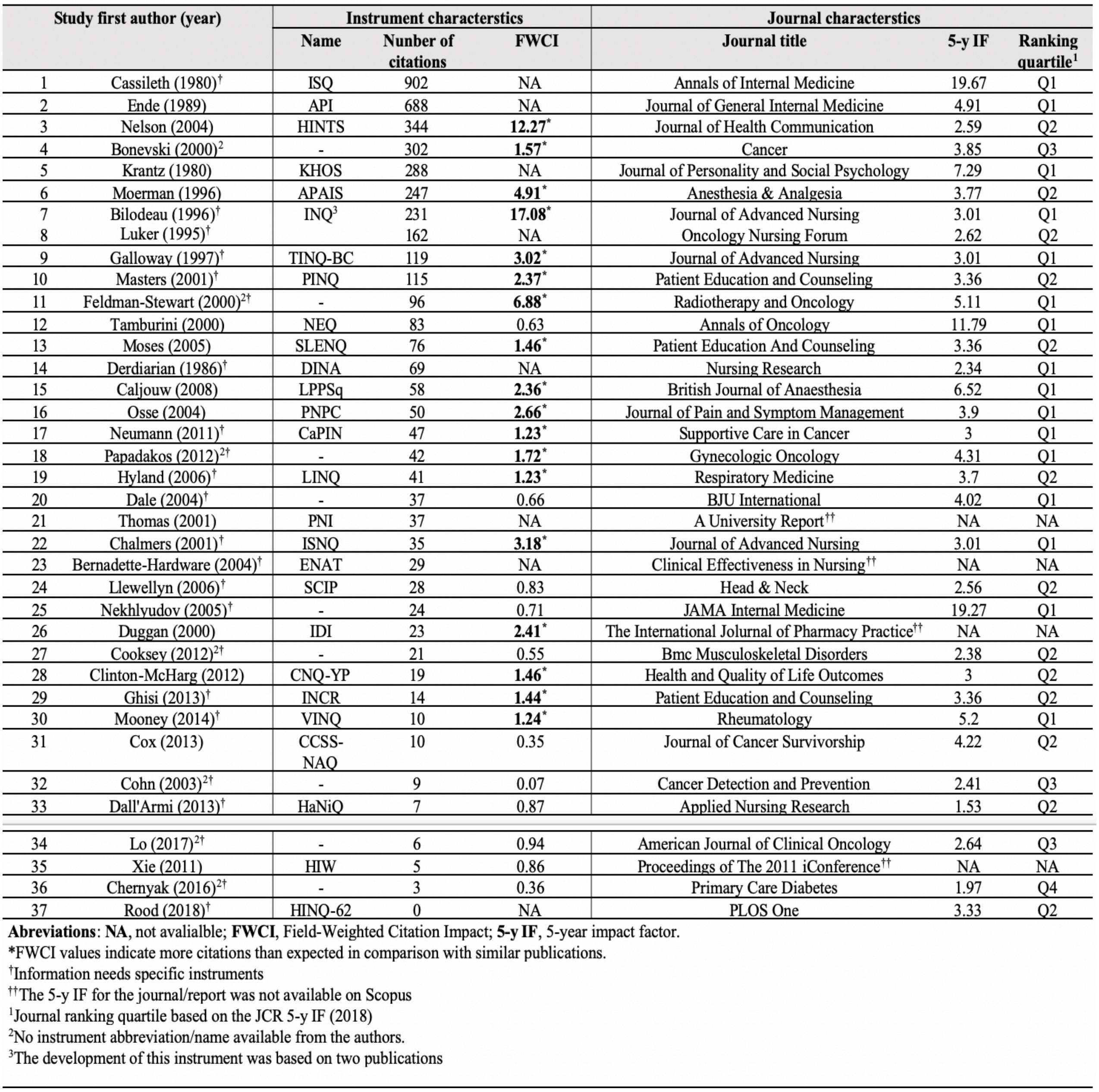
Information about time for completion, response and drop-off rates, number of missing responses, scoring methods, copyright and cost of use for these instruments were often missing and therefore omitted from the analysis.

2.3.2. Analyses of bibliometric properties related to the articles, journals and authors

The ranking for studies and instruments based on the number of citations in Scopus is shown in Figure 2-3 and Table 2-4. The total number of citations obtained by all studies was 4277, with an average of 115 citations for each study (highest=902, lowest=0). ISQ, which was developed by Cassileth et al in 1980, obtained the highest number of citations for all instruments. The next five highly-cited instruments were generic followed by commonly adapted IN-specific questionnaires; INQ (Luker et al., 1995, Bilodeau et al., 1996) TINQ (Galloway et al., 1997). The English language was used among 8 of the top 10 cited studies. The older date of publication was a predictor for more citations received in the present analysis. All of the top 10 cited studies were published more than 15 years the least ten cited instruments were published in the last eight years with no citation for the most recent study (Rood et al., 2018).

As FWCI values are only on Scopus for studies from 1996, these were not available for eight studies which however included two studies published later to 1996; a university publication (Thomas et al., 2001) and a recent study (Rood et al., 2018). Of the remaining 29 studies, 18 studies have had an FWCI value higher than 1.00, which indicates that these studies obtained higher citations than expected for similar studies in their field. The average FWCI value for the 29 studies was 2.59 (i.e. 159% than expected citations in similar studies) (Dresbeck, 2015). Bilodeau et al obtained the highest FWCI value (17.09) for their study on INQ.

Table 2-4 Ranking of instruments based on the number of citations (n=36)



Study first author (year)		Instrument characterstics			Journal characterstics		
		Name	Nunber of citations	FWCI	Journal title	5-y IF	Ranking quartile[1]
1	Cassileth (1980)†	ISQ	902	NA	Annals of Internal Medicine	19.67	Q1
2	Ende (1989)	API	688	NA	Journal of General Internal Medicine	4.91	Q1
3	Nelson (2004)	HINTS	344	**12.27***	Journal of Health Communication	2.59	Q2
4	Bonevski (2000)[2]	-	302	**1.57***	Cancer	3.85	Q3
5	Krantz (1980)	KHOS	288	NA	Journal of Personality and Social Psychology	7.29	Q1
6	Moerman (1996)	APAIS	247	**4.91***	Anesthesia & Analgesia	3.77	Q2
7	Bilodeau (1996)†	INQ[3]	231	**17.08***	Journal of Advanced Nursing	3.01	Q1
8	Luker (1995)†		162	NA	Oncology Nursing Forum	2.62	Q2
9	Galloway (1997)†	TINQ-BC	119	**3.02***	Journal of Advanced Nursing	3.01	Q1
10	Masters (2001)†	PINQ	115	**2.37***	Patient Education and Counseling	3.36	Q2
11	Feldman-Stewart (2000)[2]†	-	96	**6.88***	Radiotherapy and Oncology	5.11	Q1
12	Tamburini (2000)	NEQ	83	0.63	Annals of Oncology	11.79	Q1
13	Moses (2005)	SLENQ	76	**1.46***	Patient Education And Counseling	3.36	Q2
14	Derdiarian (1986)†	DINA	69	NA	Nursing Research	2.34	Q1
15	Caljouw (2008)	LPPSq	58	**2.36***	British Journal of Anaesthesia	6.52	Q1
16	Osse (2004)	PNPC	50	**2.66***	Journal of Pain and Symptom Management	3.9	Q1
17	Neumann (2011)†	CaPIN	47	**1.23***	Supportive Care in Cancer	3	Q1
18	Papadakos (2012)[2]†	-	42	**1.72***	Gynecologic Oncology	4.31	Q1
19	Hyland (2006)†	LINQ	41	**1.23***	Respiratory Medicine	3.7	Q2
20	Dale (2004)†	-	37	0.66	BJU International	4.02	Q1
21	Thomas (2001)	PNI	37	NA	A University Report††	NA	NA
22	Chalmers (2001)†	ISNQ	35	**3.18***	Journal of Advanced Nursing	3.01	Q1
23	Bernadette-Hardware (2004)†	ENAT	29	NA	Clinical Effectiveness in Nursing††	NA	NA
24	Llewellyn (2006)†	SCIP	28	0.83	Head & Neck	2.56	Q2
25	Nekhlyudov (2005)†	-	24	0.71	JAMA Internal Medicine	19.27	Q1
26	Duggan (2000)	IDI	23	**2.41***	The International Jolurnal of Pharmacy Practice††	NA	NA
27	Cooksey (2012)[2]†	-	21	0.55	Bmc Musculoskeletal Disorders	2.38	Q2
28	Clinton-McHarg (2012)	CNQ-YP	19	**1.46***	Health and Quality of Life Outcomes	3	Q2
29	Ghisi (2013)†	INCR	14	**1.44***	Patient Education and Counseling	3.36	Q2
30	Mooney (2014)†	VINQ	10	**1.24***	Rheumatology	5.2	Q1
31	Cox (2013)	CCSS-NAQ	10	0.35	Journal of Cancer Survivorship	4.22	Q2
32	Cohn (2003)[2]†	-	9	0.07	Cancer Detection and Prevention	2.41	Q3
33	Dall'Armi (2013)†	HaNiQ	7	0.87	Applied Nursing Research	1.53	Q2
34	Lo (2017)[2]†	-	6	0.94	American Journal of Clinical Oncology	2.64	Q3
35	Xie (2011)	HIW	5	0.86	Proceedings of The 2011 iConference††	NA	NA
36	Chernyak (2016)[2]†	-	3	0.36	Primary Care Diabetes	1.97	Q4
37	Rood (2018)†	HINQ-62	0	NA	PLOS One	3.33	Q2

Abreviations: **NA**, not avalialble; **FWCI**, Field-Weighted Citation Impact; **5-y IF**, 5-year impact factor.

*FWCI values indicate more citations than expected in comparison with similar publications.

†Information needs specific instruments

††The 5-y IF for the journal/report was not available on Scopus

[1] Journal ranking quartile based on the JCR 5-y IF (2018)

[2] No instrument abbreviation/name available from the authors.

[3] The development of this instrument was based on two publications

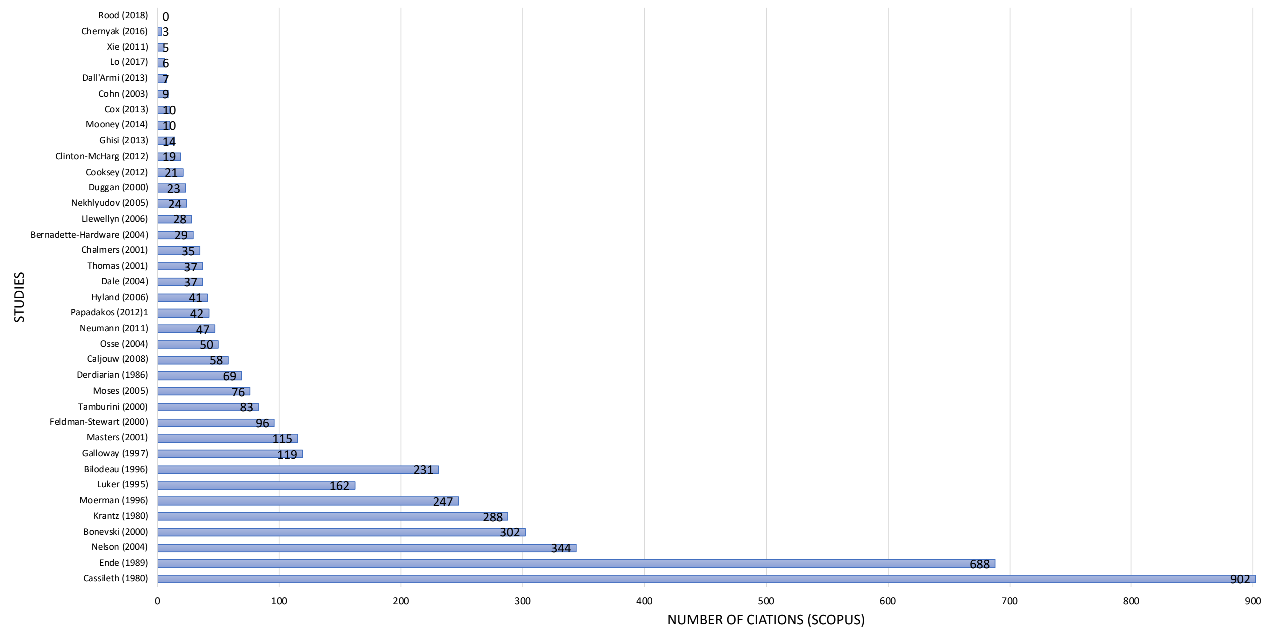


Figure 2- 3 Number of citations for each study (n=37).

Regarding the journal characteristics (Table 2-4), the average 5-year IF for the identified journals (n=33) was 4.75 with the highest IFs being with those of the Annals of Internal Medicine (19.67), JAMA Internal Medicine (19.27) and Annals of Oncology (11.79). The journal of Applied Nursing Research obtained the lowest score (1.53). The data about the 5-year IF and journal ranking was not available for four journals due to (1) discontinuation of the release [Clinical Effectiveness in Nursing (Hardware et al., 2004)], (2) a university report (Thomas et al., 2001), (3) a conference proceeding (Xie et al., 2011) and (4) lack of data on the Scopus despite the journal having been available since 1991 [The International Journal of Pharmacy Practice, (Xie et al., 2011)]. For the remaining 33 studies, 29 were ranked in the first and second quartiles based on their 2018 JCR 5-year IF.

Regarding the affiliation/s of the first author of each study, eighty-six per cent were affiliated with academic/research institutes followed by hospital care (11%) and one non-profit organisation (3%). The highest affiliated specialities were nursing and cancer care (6 studies for each) followed by psychology and psychosocial (n=5), epidemiology and public health (n=4), health education and behaviour (n=4) and non-specific (n=5). Moreover, a single study was affiliated for each of internal medicine, anaesthesia, haematology, exercise sciences and information studies.

Based on the total number of articles published in each 5-year interval, the highest number of studies (21 out of 37) were published in the ten years between 1996 and 2007 (Figure 2-4). Since then, the number has declined in the recent ten years to 12 studies from 2008 to the present time.

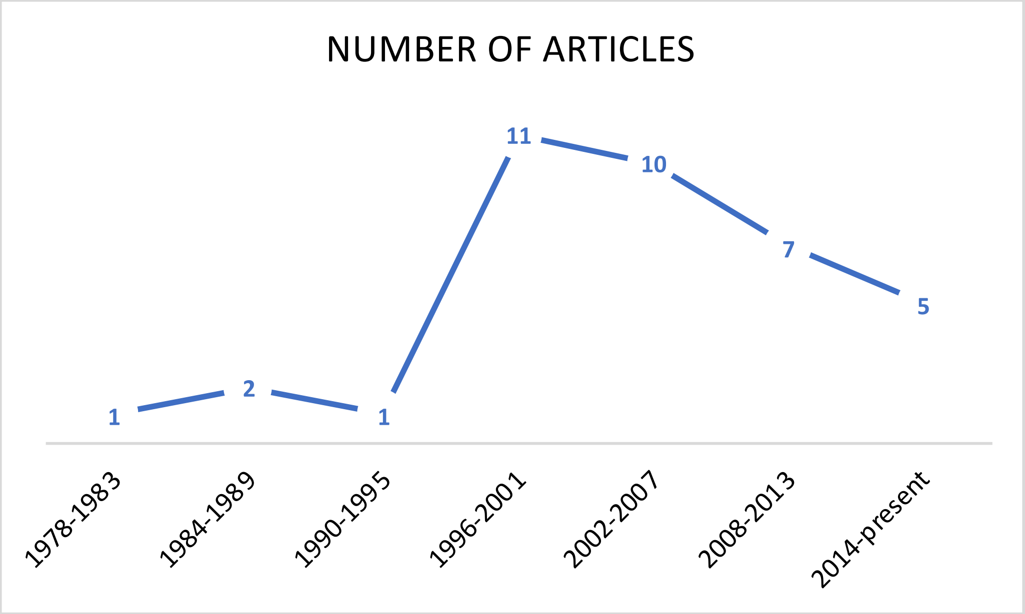


Figure 2- 4 Number of articles published in each 5-year intervals

2.4. Discussion

IN instruments as gadgets to provide patients with tailored information

There is a strong correlation between patient satisfaction and the amount of information provided by their treating clinicians (Kenny, 1995). However, clinicians usually spend less time on patient education, especially toward those with higher needs (Stirling et al., 2001). Therefore, evaluating these needs by qualitative or quantitative means may help to recognise the priority and amount of information needed and acknowledge individuals or groups with higher IN needs (Bonevski et al., 2000).

The present study identified 36 instruments that can be used to assess the patients' IN for various conditions and specialities. These can provide HCPs and researchers with a broad view on which instruments might be suitable to assess the needs and satisfaction with information solely or along with other attributes (e.g. preferences for involvement in their decision-making). The current analyses highlight the standard methods to develop an instrument, languages and length and funding sources to conduct these studies. Also, it provides useful data about the highly referenced studies as well as its impact on the field in comparison with other similar studies. Information about affiliated specialities and departments and journals' characteristics, such as its impact factors and ranking quartiles, were presented.

Interestingly, the majority of analysed studies were related to cancer patients. This might be a reflection of the conceptual theory that indicates seeking information as a coping strategy toward a serious event (Pinquart et al., 2004, Neumann et al., 2011). Indeed, addressing these concerns in cancer care has started in the early 1980s when the first specific and highest cited IN instrument (ISQ) by Cassileth et al (1980) was introduced.

After more than three decades, the burden yet continues toward the patient’s satisfaction with the presented information. For example, a recent international survey found that 35% and 47% of around 4,000 patients received insufficient information and were not actively involved in the decision-making related to treatment, respectively (All.Can.International, 2019). In contrast, providing too much information led to frustration among participants in the previous study, who wished to get information along the course of care. Hence, these findings affirm the need to maintain the patients’ autonomy and role in the clinical decision-making by assessing needs at different points of care and provide tailored and timely-oriented information accordingly (Pinquart et al., 2004, Wyke et al., 2011).

As many of the identified studies were published more than 20 years ago, there is a notable lack of qualities which may affect their quality grading using checklists such as COSMIN (COnsensus-based Standards for the selection of health Measurement Instruments) (Prinsen et al., 2018). COSMIN checklist for systematic reviews on PROMs is increasingly employed to evaluate the psychometric measurement properties such as reliability, validity and responsiveness (Assas et al., 2019). Analysing these properties was not conducted due to the heterogeneity of construct of measurement among the analysed studies (e.g. IN, behavioural involvement and decision-making). Also, the theoretical frameworks of the identified instruments were notably varied however among studies with a similar construct of measurement (e.g. cancer care), which impede the interpretation and comparisons the results (Adams et al., 2009).

Information related to the administration (interview style and completion time) and the instrument (number of items, methods of scoring, cut-off scores, cost of use and copyright) can affect the feasibility and choice of an instrument (Walton et al., 2015).

Nevertheless, many authors did not report this data and therefore analysing these was not considered in the present analysis. Likewise, reporting of the response rate, which is affected by factors related to the instrument (e.g. format and length) and respondent (e.g. fatigue and disease severity) (Rolstad et al., 2011), was often missing.

Bibliometric properties – what it tells?

Weighting the impact of publications was debated in earlier studies by Wilson (1979) and Watson (1985) which highlighted the need for further analyses related to quantity and quality of research publications. Together with the ‘publish or perish’ phenomena, the remarkable widespread use of the Web has contributed to higher research productivity and dissemination which led to higher academic productivity and publication levels (Kaminer et al., 1998, Marshall, 2000).

In line with the belief that a citation rate is significantly related to the geography of the study authors (Paris et al., 1998), the English-speaking countries contributed to eight of top 10 cited studies in the current analysis. Unlike other studies (Liu et al., 2016), the journal’s IF was not a reliable predictor for higher citations compared with the journal’s JCR ranking quartile and publication date. Journals with more specific focus tend to have higher productivity as illustrated in the present study (e.g. Patient Education and Counselling) as well as others (Oh et al., 2014, Liu et al., 2016).

Liu et al (2016) showed that clinical research is receiving less funding mainly from public or commercial bodies than basic research despite its potentially higher impact (number of citations). The industry has funded only one study of the identified studies (Hyland et al., 2006). In contrast, the non-profitable and governmental bodies had the most contributions perhaps to improve the patient’s experience and autonomy as well as better utilisation of health care resources and expenditure (Pinquart et al., 2004, Okunrintemi et al., 2017).

Several critiques might be considered when using bibliometrics as indicators for the impact of an article or journal in the present and other similar studies. For instance, some of the instruments were developed (and validated) using several publications. Second, publications with open access tend to receive more citations in comparison with non-open access (Sotudeh, 2019). Moreover, a journal IF may not be necessarily a valid indicator for an article’s impact (Belter, 2015). Therefore, it is recommended to use the bibliometrics indicators carefully and integrate it with other methods, such as peer review or a panel of experts, to overcome the weakness of a single method and to present fair and balanced views when assessing the scientific publication (Belter, 2015),

In the present time, there are more advanced methods available to weight the impact of a publication such as the complementary metrics to track and analyse the online activity including article usage in websites (i.e. clicks, views, downloads, captures and mentions) and social media (likes, shares and comments, ratings, scores and tweets). Examples of this include Altemetrics and Altemetric Explorer (www.altmetric.com) and Plum X (https://plumanalytics.com). Institutions, publishers, research funders and R&D departments are increasingly utilising these methods for their data-driven strategies, public engagement policies and promotion and tenure of academics and researchers. However, the use of such methods is however subject to bias and therefore interpreting the results needs to be accompanied by traditional metrics (Warren et al., 2017, Cabrera et al., 2018).

Study strengths and limitations

Strengths included presenting useful information for HCPs and researchers on which instruments suitable to determine the needs for information in a specific field of health care (e.g. cancer care) or chronic disease (e.g. diabetes mellitus). Secondly, patient needs can differ based on determinants related to the disease (life-threatening, severity, time since diagnosed and impairments) and the individual (gender, age, socio-economic status and health literacy) (Derdiarian, 1986, Salmon et al., 2009). Therefore, this data can also help the health care policymakers to develop interventions for patients or groups with higher needs and support their active participation in own health care decisions by delivering tailored information (Bonevski et al., 2000, Mooney et al., 2014, Chernyak et al., 2016).

The present study however focuses on primary studies and their uses, rather than addressing questions related to its measurement properties. Selection bias and subjective evaluation for the present study were reduced by adapting search methodologies from previous research. For example, using the COSMIN checklist for data representation and using more than one quality indicator for each instrument (number of citations and FWCI) and journal (5-year IF and JCR ranking quartile). The lack of reflection of whether these instruments are measuring what it is proposed to measure (valid) or free of measurement errors (reliable) may limit the study's practical implications. Recently, Gondivkara et al (2019) noted a lack of studies with high methodological quality to assess PROMs. As psychometric properties of an instrument affect its selection (Haywood et al., 2016), further studies may consider evaluating these qualities of disease- or discipline-specific instruments using methodologies introduced by COSMIN to assess the content validity (Terwee et al., 2018) and systematic review for PROMs (Prinsen et al., 2018).

2.5. Conclusion

The present study a concise description of 36 instruments that can be useful to assess IN for different health conditions and care settings. Generic instruments included items of IN while assessing other variables including pre-operative anxiety, preferences for decision-making, behavioural involvement and other needs related to a specific care setting. In contrast, IN-specific ones considered the assessments mostly in cancer care in addition to cardiology, endocrinology, pulmonology, radiology and rheumatology. Both of the generic and IN-specific instruments were mostly available in the English language which reflects the origin of their development. Previous instruments and literature review were the most conventional methods for developing these instruments, respectively. Non-profit organisations contributed the highest to fund these studies.

The date of publication was a reliable predictor for the number of citations received with an average of 115 for each study and FWCI average value that indicates 159% higher chance of receiving citations than expected for similar studies. IFs varied considerably between journals with the highest at 19.27 and the lowest at 1.53. The highest affiliated specialities included nursing, cancer care and psychology. Studies were mostly published in the period between 1996 and 2007. Limitations and future recommendations toward the use of bibliometric indicators were highlighted. Perhaps these instruments can be better implemented with the increased use of technologies based on the web, mobile and wearables technologies to recognise the patient's needs and implement the necessary interventions accordingly (De Simoni et al., 2014, Adu et al., 2019, Bove, 2019).

CHAPTER III. DEVELOPMENT OF THE INFORMATIONAL NEEDS QUESTIONNAIRE ORAL EPITHELIAL DYSPLASIA (ODIN-Q)

3.1. Introduction

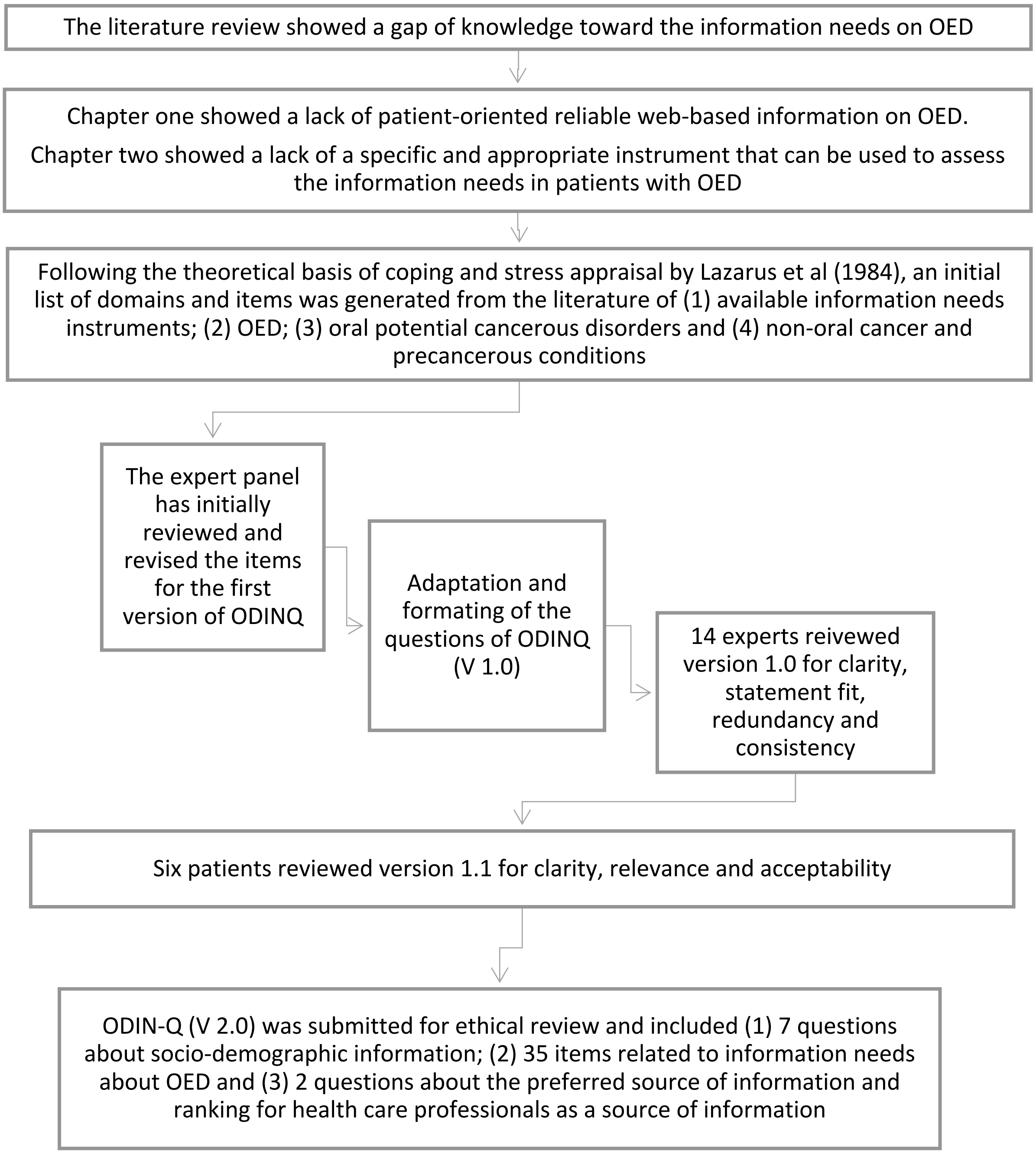
Health information can encourage active engagement of patients in health decision-making and reduce the possibility of preventable disease (Gruman et al., 2010, Smith et al., 2015). Informed patients experience less uncertainty than less informed individuals that can, in turn, improve their satisfaction, coping strategies and treatment outcomes (Feldman-Stewart et al., 2000, Neumann et al., 2011, Ormandy, 2011). Despite the immense use of the Internet, health care professionals (HCPs) probably remain the most reliable source of health related information as the information available on the world wide web may be of poor quality, be difficult to read and understand and lacks actionability (Alsoghier et al., 2018). Nevertheless, there is often a gap between information needed by patients and that provided by their attending clinicians, and hence a risk of poor shared decision-making between the patient and HCPs (Weymann et al., 2016).

Closing such a gap requires the delivery of tailored information based up on a patient’s true needs and preferences (Luker et al., 1995, National Institute for Clinical Excellence, 2012, Foster et al., 2015, Kassianos et al., 2016). One increasingly common method to do so is to acquire this information by using patient-reported experience measures (PREMs) such as informational needs (IN) instruments (Halkett et al., 2007, Dall'Armi et al., 2013, Alamanou et al., 2016). The comprehensive literature review showed the importance to identify and meet the patient’s IN concerning oral epithelial dysplasia (OED). Chapters one and two showed the lack of highly reliable web-based and organisational sources of information about OED and indeed the absence of instruments that can specifically assess the sufficiency and importance of information given about OED.

Therefore, the primary objectives of the present chapter are to develop and validate the Oral Epithelial Dysplasia Informational Needs Questionnaire (ODINQ) and to assess what are the information needs (IN) concerning OED and which information considered important in a cohort of patients with OED. Secondary objectives aim to answer questions such as what the preferred sources are to receive information about OED and who has unmet information needs and what clinical and demographic factors associated with unmet needs.

3.2. Methods

This is a prospective, observational questionnaire-based quantitative study conducted from October 2018 to November 2019 at UCLH, Eastman Dental Hospital, Oral Medicine Unit. Based on the timeline of the study, the following sections present the performed actions from developing ODIN-Q (Figure 3-1) to the plans for validation and statistical analyses.



The literature review showed a gap of knowledge toward the information needs on OED

Chapter one showed a lack of patient-oriented reliable web-based information on OED.

Chapter two showed a lack of a specific and appropriate instrument that can be used to assess the information needs in patients with OED

Following the theoretical basis of coping and stress appraisal by Lazarus et al (1984), an initial list of domains and items was generated from the literature of (1) available information needs instruments; (2) OED; (3) oral potential cancerous disorders and (4) non-oral cancer and precancerous conditions

The expert panel has initially reviewed and revised the items for the first version of ODINQ

Adaptation and formating of the questions of ODINQ (V 1.0)

14 experts reivewed version 1.0 for clarity, statement fit, redundancy and consistency

Six patients reviewed version 1.1 for clarity, relevance and acceptability

ODIN-Q (V 2.0) was submitted for ethical review and included (1) 7 questions about socio-demographic information; (2) 35 items related to information needs about OED and (3) 2 questions about the preferred source of information and ranking for health care professionals as a source of information

Figure 3-1 Schematic representation of the steps performed to develop ODIN-Q.

3.2.1. Development of ODIN-Q

- The theoretical framework of the ODIN-Q:
    - The development of ODIN-Q was guided by the stress and coping theory (Lazarus et al., 1984) which suggested that dealing with stressful events

[e.g. receiving a diagnosis with oral precancer] requires multiple behavioural and cognitive strategies adopted by individuals.

  - These approaches include seeking information to understand the new health-related encounter and its effect on their well-being and to maintain emotions while experiencing the alarming event (Lazarus et al., 1984, Galloway et al., 1997).
  - This theory was sought to be suitable to guide investigating IN in patients with of a potentially cancerous disorder of the oral cavity in view of its common adaption by similar studies on potentially cancerous lesions [e.g. abnormal pap smear (Rask, 2017a)] as well as cancer-related IN studies of the breast (Galloway et al., 1997), colon (Galloway et al., 1996), head and neck (Semple et al., 2002) and prostate (Davison et al., 2002).

- The initial list of items for ODIN-Q
  - The items for ODIN-Q were adapted and modified from the following:
    i. The reliable, valid and highly adopted IN instruments for patients with metastatic disease [ISQ, (Cassileth et al., 1980)], breast cancer [TINQ-BC, (Galloway et al., 1997) and INQ, (Luker et al., 1995, Bilodeau et al., 1996)] and prostate cancer (Dale et al., 2004).
    ii. Items reported in quantitative and qualitative studies of OED, oral potential malignant disorders (OPMDs) (Lin et al., 2015, Tadakamadla et al., 2017b, Tadakamadla et al., 2017a), oral cancer or its symptoms (Scott et al., 2009b, Noonan, 2014, Allen et al., 2015, Inglehart et al., 2016) as well as non-oral cancer (Tariman et al.,

2014, Dobson, 2016) and precancerous conditions (Rask et al., 2017).

  - The initial domains for ODIN-Q were adapted from TINQ-BC (disease, investigative tests, treatments, physical, finances and psychological) in addition to a medical system domain and access to information domain from a study by Fletcher el al. (Fletcher et al., 2017).
  - The unnecessary items were omitted, such as these related to cancer while others related explicitly to OED were added.
  - When considering the scale properties for ODIN-Q, the core study team (AA, RNR and SP) considered the dual scales recording patient preference for information and the amount of information received as seen in Dale's IN questionnaire for prostate cancer most appropriate (Dale et al., 2004).
  - At this stage, 58 items were categorised under eight domains (Disease, Investigative Tests, Treatments, Physical, Psychosocial, Family and Finances, General health, Medical System and Access to Information) (Appendix 2).

- ODIN-Q (version 1.0)
  - Questions were formulated and revised by a consensus panel of the core study team (AA, RNR and SPR).
  - This version includes

  i. 11 questions about socio-demographic variables (age, gender, marital status, town/postcode, ethnicity, religion/spiritual support (optional), educational level, employment status, total personal income before all deductions, smoking, and alcohol).

ii. 58 questions about IN which however were not labelled under domains as agreed initially by the study team. The dual scale format was maintained for each question with two 4-point scales; the amount of information received since being diagnosed with OED (too much, enough, not enough, none) and whether a question is important (very, yes, not very, not at all).

- One question about the preferred source of information and an additional question to rank of HCP as the source of information about OED if the participant selects one-to-one in the earlier question.

3.2.2. Content and face validity of ODIN-Q by experts (n=14) and patients (n=5)

It is defined as *'the degree to which elements of an assessment instrument are relevant to and representative of the targeted construct for a particular assessment purpose'* (Haynes et al., 1995). The content validity of an instrument is commonly obtained by experts' judgments (Jensen, 2003).

Experts review of ODIN-Q (content validity part 1)

The initial version of ODIN-Q (v 1.0) reviewed by a panel of Oral Medicine experts to confirm its content validity. Specific instructions with regards to the content review included questions about its clarity [*is the questionnaire clear?*], relevance [*do the items match the topic (i.e. information needs of patients with oral epithelial dysplasia)?*], redundancy [*are any of the items redundant/repetitive?],* and acceptability [*do the items in the questionnaire also seem to be asking about the same general topic?*] (Appendix 3). This form was based upon an earlier work by Mastaglia et al (2003) which highlighted the need to ensure that the items of a questionnaire should reflect its conceptual construct accurately and comprehensively possibly using a checklist of four specific criteria [clarity, statement fit, redundancy and consistency] (Mastaglia et al., 2003). If an expert answered no for any of these questions, space was provided to indicate which item/s warranted revision.

Fourteen experts, who did not otherwise participate in the development of ODIN-Q, provided their feedback up on the initial ODIN-Q (v 1.0). The characteristics and feedback from the participated experts are shown in Table 3-1. Out of the 14 experts, 8 were males (57%) and 7 (50%) and 6 (42%) had a speciality training and/or a PhD, respectively. The experts were currently practicing in 6 different countries including the UK (n=7), Ireland (n=2), Portugal (n=2), Australia (n=1), Brazil (n=1) and Italy (n=1). All experts had had six or more years in practice after obtaining their first professional degrees.

Table 3-1 The demographic and educational background of the experts (n=14)

Variable	Category	Number of participants (%)
Gender	Male	8 (57%%)
	Female	6 (43%)
Postgraduate qualifcation (one or more choice)	Higher diploma	2 (14%)
	Speciality training	7 (50%)
	MSc/MS	4 (29%)
	PhD	6 (42%)
	Others *(MD, speciality training and no postgraduate degree*)	5 (36%)
Years in practice (after the first professional degree)	Less than 2 years	0 (0%)
	2-5 years	0 (0%)
	6-10 years	2 (14%)
	More than 10 years	12 (86%)

Country of practice	UK	7 (50%)
	Europe	5 (36%)
	Others	2 (14%)

Figure 3-2 shows the feedback from 13 experts using the evaluation forms for ODIN-Q (version 1.0). The majority of experts (84%) considered the questionnaire to be clear and the items asked about the same general topic. Nevertheless, around half of the participant noted a redundancy and irrelevance of specific items which indicated the need for further revision of version 1.0 of ODIN-Q. One expert (expert ID, 11), did not complete the evaluation form but provided some comments and therefore, was included in the content study.

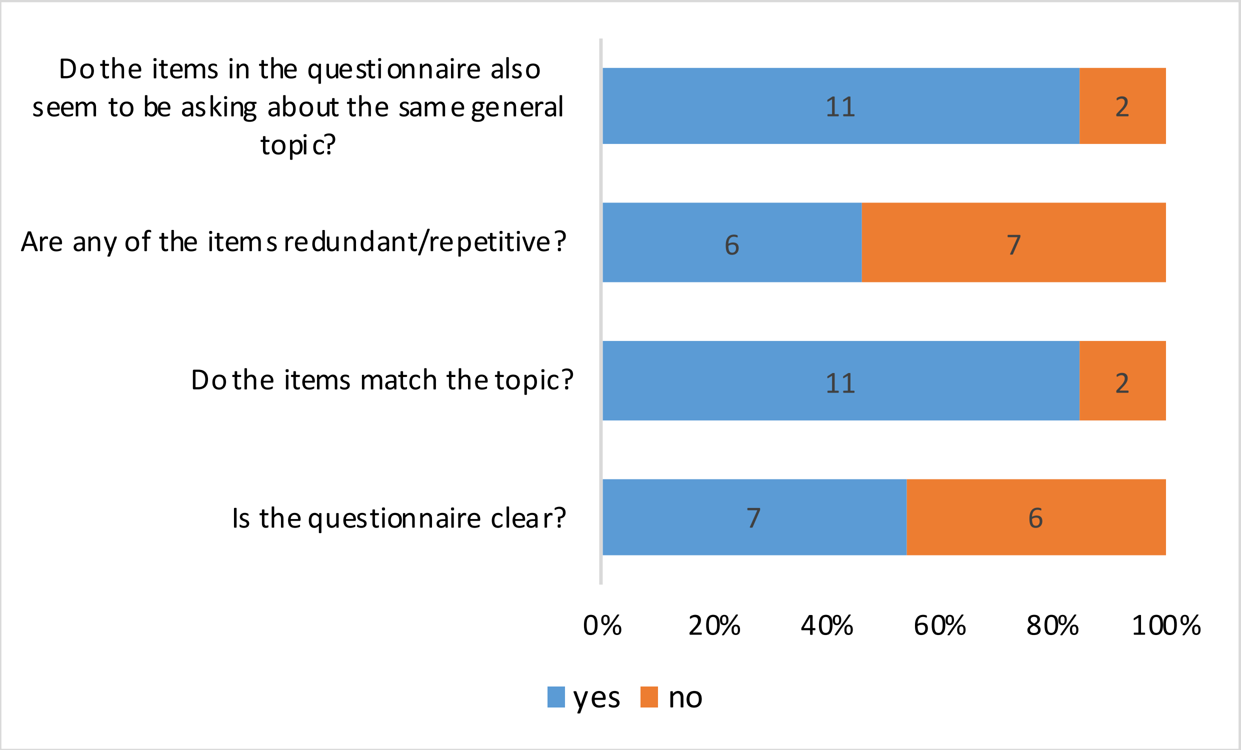


Figure 3-2 Visual representations of the experts’ responses to the evaluation questions (n=13)

The unclear, irrelevant, redundant, and unacceptable items were omitted after reviewing the experts' feedback by the study team (AA, RNR and SRP). There was some agreement between the experts as toward the length of the questionnaire (e.g. number and length of items) and using medical jargons (e.g. clinical features). The list of actions for each comment is indicated in Table 3-2.

Table 3-2 Examples of the comments given by experts for ODIN-Q (version 1.0)

Expert's ID	**Comment/s**	**Action taken**
05	*Not sure what is meant by "fear of recurrence or progression to cancer"*	The word recurrence was omitted as it fits cancer more than OED
06	*Some grammatical errors in many of the questions making the questions less clear but if these are addressed will be easier for patients to understand and answers*	The items were revised grammatically by the study team (RNR, SRP and AA)
	Would it be worth adding some explanation of what units refer to in relation to various alcoholic drinks for benefit of some patients?	The NHS Guide to Alcohol Units was added to the demographic section
	I wonder if all patients will feel able to complete because of there being so many to answer	The 58 items were shortened, combined or omitted to 37 items based on the received feedback
07	*I think that it is too long to keep a patient attentive*	The 58 items were shortened, combined or omitted to 37 items based on the received feedback
08	*"Clinical features" is an expression that probably means nothing for someone without medical background*	The question 'What are the clinical features of OED?' was replaced by 'how it looks inside the mouth'
	My suggestion is to test the questionnaire with a group of people with demographic characteristics similar to the group you expect to survey, but without any medical background	The pilot study was planned with 6 patients before administering the final version of ODIN-Q (version 2.0)
09	*Although I marked yes, I would possibly expand the first section of the questionnaire related to background of patients*	Further information was obtained for the proposed study from each participant's electronic and paper medical records using clinical finding forms (Appendix 4)

10	*Patients may have difficulty understanding “Units of alcohol” without a guide to what this means in terms of alcoholic drink volumes*	A link was provided to the NHS guidance to calculate alcohol units (NHS, 2018) and schematic representation from the Alcohol questionnaire (University of Reading, 2018) to the demographic section to ODIN-Q
	“Degree of importance” does this mean the degree of importance to that individual patient or the degree of importance with respect to what society needs to know about the population in general?	The scale title ‘degree of importance’ was replaced by *‘is this item important to you’* on the top of each domain
11	*Ethnicity: if you insist on this, then use the same data collection format that your own trust uses in employment questionnaires*	The NHS format for ethnicity was added
	This is a huge number of questions	The 58 items were shortened, combined or omitted to 37 items based on the received feedback
	Why marital status, postcode, religion and income? Relevance?	The study team agreed to drop these variables due to low relevance/value to the proposed study
12	*Some questions contain jargon which may not be understood by patients… (e.g. clinical features)*	The question ‘What are the clinical features of OED?’ was replaced by ‘how it looks inside the mouth’
10	*“How the OED acts in the body?” I think that this is an odd question, and I am not sure if my patients would understand this. Also, I would not put this as the first question.*	This item was replaced by ‘W*hat is likely to happen to OED in the future’* and moved to the end of ‘information about the disease’ domain (Q10)

Patient review for version 1.1 of ODIN-Q (Face validity)

Face validity, which is an aspect of content validity, was determined by a purposive sample of patients attending Oral Medicine Clinics at Cork University Dental Hospital in Ireland. The pilot study protocol had been approved by the Clinical Research Ethics Committee on 26th October 2017. Five male (n=3) and female (n=2) patients with a mean age of 60 years (38-73 years) were consented and requested to complete ODIN-Q (v 1.1) and its evaluation form.

The clinical findings form (Appendix 4) was used to record information about clinical features such as the date since the first diagnosis of OED, associated oral conditions and lesion characteristics (site, size and intervention) (Table 3-3).

Table 3-3 Demographic and clinical variables of participant patients of the pilot study (n=5)

ID	**Demographics**						**Clinical features of OED**				
	Gender/ age	*Ethnicity*	*Education*	*Employment*	*Smoking*	*Alcohol (units per day)**	*Date of the first diagnosis*	*Oral condition*	*Site*	*Degree*	*Intervention*
C1	M/38	White - Irish	High school diploma	Self-employed	Never	Never	March 2017	OL	Tongue (ventral)	Mild	Surgery
C2	M/60	White - Irish	Bachelor's degree	Retired	Never	Past	January 2018	OL	Floor of the mouth	Mild	Monitoring
C3	F/73	White - Irish	High school diploma	Housewife	Never	Never	February 2018	OLP	Tongue (dorsum)	Mild to moderate	Surgery
C4	M/67	White - Irish	Bachelor's degree	Retired	Current (20 cig/d)	Current (5 to 6 u/d)	December 2017	AC	Lower lip	Moderate	Surgery
C5	*M/66*	White - Any other	Bachelor's degree	Retired	Never	Current (1 to 2 u/d)	June 2017	AC	Lower Lip	Mild	Surgery

*In a typical day.
Abbreviations: **M**, male; **F**, female; **OL**, oral leukoplakia; **OLP**, oral lichen planus; **AC**, actinic cheilitis

Although the included patients were only those with White Irish ethnicity, this step was sought necessary to perform an 'overall' and subjective evaluation of the newly developed ODIN-Q (de Vet et al., 2011). It was also a practical approach as completing ethics paperwork in Cork, Ireland was initially faster than the equivalent in London, the UK possibly due to a fewer number of reviewed applications.

Face validity aims to examine the overall view of the content (de Vet et al., 2011). It is defined as '*The degree to which (the items of) an HR-PRO [health-related patient-reported outcomes] instrument indeed looks as though they are an adequate reflection of the construct to be measured'* (Mokkink et al., 2010b). At the time when the study was planned, there was no available method to assess or quantify the face validity (October 2017-April 2018), however, a Delphi study was subsequently published and provided standardised methods to assess the content and face validity (Terwee et al., 2018).

An evaluation form similar to that used for experts was modified to include questions about clarity (*is the questionnaire clear?*) and relevance (*is the questionnaire related to your condition?*). Questions about redundancy and consistency were replaced by a question about acceptability (*in general, do you find the questionnaire acceptable?)* to broadly review the content (face validity) and improve its comprehension by participants. The patients requested to consider the following issues; re-wording and shortening questions, changing a technical term (cognitive), adding 'not applicable' choice for those who were retired and omitting questions related to insurance and spiritual and religious needs support (Table 3-4).

Table 3-4 Examples of the participants' feedback for ODIN-Q (v 1.1) (n=5)

Criteria	Feedback	Action taken/explanation
Clarity	*Overall clear*	None
	Wording is weird in the "Why and why not the OED is being treated?"	The item was reworded to '*what will happen if it is not treated?*'
	I understand "cognitive" but I'm not sure other people will	The question '*how to deal with the emotional and cognitive disturbances?*' was changed to '*how to cope with the possible effects of the disease/treatment?*' under '*psychosocial aspects of OED'* domain
	Not applicable for job and career please as some of us are retired	The following was added to the question about the effects on job/career; '*N.B. If you are no longer working, please skip to question 28.*'
	I don't have health insurance – will that make me ineligible for treatment?	The question about health insurance was removed as it will be less relevant to the proposed single centre NHS-based study
Relevance	*Not much point in getting information about screening when I have it already*	The item was however kept as the purpose of ODIN-Q was to assess the satisfaction and needs which will be used to develop patient-tailored information leaflet.
	The treatments I was offered were cut it out or watch…so I don't know how "When and how to know the treatment is working?" are relevant to me	The item was replaced by '*what are the chances of a cure?'*
Acceptability	*Don't think it is acceptable to discuss spiritual and religious things with the doctor*	The item about spiritual and religious support was omitted
	Don't think having a white patch in my mouth makes me less sexually attractive so wouldn't find that acceptable	The item was kept considering the possible effects of OED or its treatment on the lip
	This is too long	Two items were removed and others underwent further reduction of words and syllables to shorten the revised version of ODIN-Q (v2.0)

Further revisions were made for other items to enhance the readability level and score from 5th grade level (Kincaid et al., 1975) and Flesch Reading Ease Score at 58 (0=hardest and 100=easiest) (Flesch, 1948) of the first version to the 4th grade level and a score at 69 in the later version of ODIN-Q, respectively. Both were measured by an online readability calculator (https://readable.com). Following the changes made based on the feedback from experts and patients, the study team constructed the complete version of ODIN-Q (v 2.0) which included:

i. *Socio-demographic section:* participants were asked to complete seven questions that concern age, gender, ethnicity, educational level, employment status, and smoking/alcohol intake.

ii. *Information needs section*: this includes 35 questions about IN represented under seven domains; general information, investigative tests, treatments, physical aspects, psychosocial aspects, medical system and access to information.

iii. *A multiple-choice question:* the preferred source to receive information about OED from (i.e. one-on-one meeting, walk-in help centre, group information session, printed information materials, World Wide Web, TV/radio, and DVD/audio recording). If one-on-one meeting choice is ticked, the participant will be asked to rank health care professionals who they wish as their source of information such as general dental practitioner, general practitioner, OED specialist (e.g. oral medicine, oral surgery, or ENT), and auxiliary medical staff (e.g. medical or dental nurses).

iv. An open-ended question to indicate other topics not included in the list.

A summary of general information and scoring for the version 2 of ODIN-Q is shown in Table 3-5.

Table 3-5 Background information of ODIN-Q (version 2.0).

Name of the Instrument	Oral Epithelial Dysplasia Informational Needs Questionnaire (ODIN-Q) [version 2.0]
General information	
Construct/ intended application	Information needs/clinical and research settings
Population	Patients with oral epithelial dysplasia
Mode and type of measurement	A paper-based and self-administered questionnaire
Language	English
Number of items	7 questions for demographic data, 35 items for information needs, 2 questions for the preferred sources of information and an open-ended question
Response options	A 4-point grading system for both of the amount of information received (too much to none) and importance (very important to not very important) scales
Copyright	No copyright needed to use ODIN-Q
Scoring method and interpretation	
Method of scoring	1. Amount of information received since being diagnosed (scale 1); too much=4; enough=3; not enough=2 and none=1. 2. Importance (scale 2); very=4; yes=3; not very=2 and not at all=1 (Dale et al., 2004).
Score presentation	• Summing the scores for each item, domain or overall score. • The total score for each ODIN-Q scale is 140 and the lowest is 36.
Score interpretation and cut-off score	• A high score represents ‘enough’ and ‘important’ information, respectively for items, domains or the overall score. • A sum score lies below the median of the total score set will be considered as a case (i.e. unmet information needs and unimportant information item, respectively) (Meesters et al., 2011). • As the highest total score is 140 and the lowest is 35, the interpretation will be as follows: **Scale 1 (amount of information received)** ➢ 140-114= too much information received on most items ➢ 113-88= enough information received on most items ➢ 87-62= not enough information received on most items *(case: unmet IN)* ➢ 61-35= no information received on most items *(case: high unmet IN)* **Scale 2 (degree of importance)** ➢ 140-114= Most items considered important ➢ 113-88= Many items considered important

	- 87-62= Some items might not be important *(case: some unimportant items)* - 61-35= Most items are not important *(case: many unimportant items)* - If an item is considered not applicable, the scores of this item will be deducted from the total score (i.e. omitting 4 points from the total score).

3.2.3. Validation study for ODIN-Q

Study design

This was a prospective, observational questionnaire-based quantitative study. Participants were patients diagnosed with OED as per current standard diagnostic criteria (El-Naggar et al., 2017) and attending the Oral Medicine clinics of the UCLH Royal National ENT and Eastman Dental Hospitals as well as Head and Neck Clinics of UCLH Macmillan Cancer Centre, respectively.

Inclusion Criteria

1. Adults aged 18 or above at the time of the screening visit, good command of English language both written and spoken.
2. Being able to consent.
3. No concurrent malignancy in the head and neck or elsewhere.

Exclusion Criteria

1. Individuals under 18 years old.
2. Unable to speak and read English.
3. Concurrent malignancy in the head and neck or elsewhere.

4. Clinical judgement (e.g. individuals diagnosed with a debilitating disorder which may affect the responses to ODIN-Q).

For sample size calculation, there is no present consensus to determine the sample size for the validation of a patient outcome measure (Anthoine et al., 2014). However, the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) checklist for study design of PROMs suggests that a sample size, based on a generic guidance (Mokkink et al., 2018b), can be excellent (≥100 participants), good (99-50), fair (49-30), or poor (<30) (Mokkink et al., 2019). This checklist was followed to validate each psychometric property of ODIN-Q based on a 4-point rating scale. This checklist evaluation is not desired to provide an overall rating however it was employed to illustrate the necessary steps undertaken to develop ODIN-Q.

Quality control

Missing values are frequently observed in questionnaire research and there is no consensus on how to deal with these values to avoid misleading results. A simple and commonly adapted method is to substitute these values with the mean of the available scores of a related construct (Bethlehem, 2009, Janet et al., 2010, Riffenburgh, 2012b, Rask, 2017b). Therefore, the following approaches were followed:

- Questionnaires’ responses with ≥11% non-response for each scale of ODIN-Q: the questionnaire was excluded from analyses.
- Questionnaires’ responses with ≤10% non-response for ODIN-Q: values were matched to the average answer of the same item for all participants.

- Missing data in test-retest version of ODIN-Q:
    - Questionnaires with more than four missing values were excluded from the analyses.
    - If four or less, the individual responses were matched to the average score of the same item for all participants.
- Missing values of demographics and clinical findings: the variable were omitted from the analysis.

3.2.4. Data analysis and representation

Descriptive statistics

The responses to ODIN-Q were transferred as scores using Microsoft Excel (version 16.29.1) as follows

1. Amount of information received since being diagnosed (scale 1); too much=4; enough=3; not enough=2; none=1 and not applicable=0.
2. Importance (scale 2): very=4; yes=3; not very=2; not at all=1 and not applicable=0.

Means, medians, standard deviations, highest and lowest values and percentages were used to describe the study characteristics were calculated using IBM Statistical Package for Social Sciences (SPSS) software (version 22.0). Also, the response and completion rates were calculated.

Correlations between the patient's IN and demographics and clinical variables

Patient attributes were classified in subgroups to compare these with mean scores of both subscales of ODIN-Q (i.e. the amount of information received and degree of importance scales of ODIN-Q). Furthermore, the total score of the amount of information received subscale was categorised to (1) four categories - including too much information, enough information, not enough information and no information received; (2) two categories as having enough (met IN) and insufficient information (unmet IN) and (3) as a numerical scale. The patient's attributes in each subgroup were analysed for associations with clinical characteristics by performing stepwise linear and logistic regression based on the type of outcome [continues numeric and binary or ordinal variables, respectively]. Variables with statistically significant level ($p < 0.05$) in the previous univariate analyses were considered for the multivariate logistic regression analyses (Heisler et al., 2003, Elkin et al., 2007, Amarasinghe et al., 2010).

These variables were collected using the following forms:

- Socio-demographic section of ODIN-Q (patient-based); age, gender, ethnicity, education, employment, smoking and alcohol units
- Clinical findings form (clinician-based); the number of associated general and oral conditions, number of medications, number of biopsies which showed OED, number of sites affected by OED, time since the first diagnosis, predisposing OPMD as well as information for each OED lesion (the site, degree and type of intervention).

Normality of data distribution was tested by Shapiro-Wilk test (Shapiro et al., 1965) and Pearson's or Spearman's correlation coefficient (two-tailed test of significance) was used to measure correlations between the variables (Overholser et al., 2008). Values were interpreted based on the Guilford's interpretation as low [0.20-0.40], moderate [0.40-0.70] or high [>0.70] (Guilford, 1950).

Psychometric analysis for ODIN-Q

There are no standardised statistical methodological tests available to assess and validate an informational needs questionnaire. However, the recently developed checklists by COSMIN to assess the psychometric properties of PROMs were adapted for ODIN-Q validation. The assessed properties of ODIN-Q included reliability (internal consistency and test-retest) and validity (content and construct) (Table 3-6) (Prinsen et al., 2018, Terwee et al., 2018).

Table 3-6 Assessments of psychometric properties of the ODIN-Q.

Criteria	Definition, interpretation and methods
Reliability	Defined as '*the degree to which the measurement is free from measurement error*' (Terwee et al., 2012).
	Internal consistency • Internal consistency is measured through Cronbach's α which measures the level of agreement between items in a subscale or domain based on scores from 0 to 1 (0=no agreement, 1=perfect agreement) (Cunningham et al., 2013). • Values of Cronbach's coefficient are interpreted as excellent (>.90), good (>0.80), acceptable (>0.70), questionable (>0.60), poor (>0.50) and unacceptable (<0.50) (Mallery et al., 2003).
	Test-retest reliability • To determine the scale repeatability participants were asked to complete the ODIN-Q one week after their initial attempt. • Participants were asked to complete these at home and return the completed ones using the given pre-paid envelopes. • Upon returning the week 2 questionnaire, the responses were computed using the weighted Cohen's kappa coefficient with linear weighting scheme for ordinal scales (Cohen, 1968, Streiner et al., 2015). • Based on Cicchetti and Sparrow's interpretation for kappa's values, these were interpreted as excellent (0.75 or higher) good (0.74-0.60), fair (0.59-0.40) and poor if below 0.40 (Cicchetti et al., 1981).
Validity	This is defined as *'the degree to which an instrument truly measures the construct(s) it purports to measure'* (Terwee et al., 2012).
	Content validity • Defined as *'the degree to which the content of a measurement instrument is an adequate reflection of the construct to be measured'* (Terwee et al., 2012).

- The content validity of ODIN-Q was assessed by clinicians for clarity, statement fit, redundancy and consistency and the items were revised and reduced from 58 to 37 questions.
- Similarly, patients also assessed the revised version of ODIN-Q for clarity, relevance and acceptability which led to 35 items in the revised version (see section methods 3.2.2).

Construct [structural] validity

- Defined as*' the degree to which the scores of a measurement instrument are consistent with hypotheses'* (Terwee et al., 2012).
- Exploratory factor analysis (EFA) was used to describe the inter-correlations of items and subscales in each scale of ODIN-Q and to ensure its correspondence to conceptual constructs (McDowell, 2006).
- Similar to the methods used by Dale et al (2004) , the factors were extracted following principal components methods as well as using varimax method for rotation.
- Two tests were performed to ensure the adequacy of data for EFA; (1) Kaiser-Meyer-Olkin Measure of Sampling Adequacy with a minimum accepted value > 0.50 and (2) Bartlett's test of sphericity which needs to be statistically significant ($p < 0.05$) (Hair et al., 1998, Field, 2013).
- Factors with eigenvalues higher than 1.0 were retained and weighed as important (Bowling, 2014).
- Despite no consensus available for factor loadings from EFA, the decision to exclude/retain items from both scales was based on a minimum factor loading of 0.4 for both scales (Comrey et al., 1992, Maskey et al., 2018).

Construct [Hypothesis testing] validity

- This reflects the relationships between the scores of the tested instrument in comparison with another instrument that measures similar or dissimilar construct among the individuals (de Vet et al., 2011).

- Discriminative validity (comparisons between the subgroups) (Mokkink et al., 2019):
    - The ODIN-Q scores were compared using regression analyses based on the demographic and clinical variables of the subgroups to accept or reject the pre-defined study hypothesis of stress and coping theory (Lazarus et al., 1984).
- Convergent validity (comparisons between ODIN-Q and another instrument that measures a similar construct) (Mokkink et al., 2019):
    - Krantz Health Opinion Survey (KHOS) (Krantz et al., 1980) is one of the highly used and validated instruments to measure to assess the preference for information (KHOS-I, seven items) and active involvement in own health care decisions (KHOS-B, nine items) based on a binary scale (agree=1/disagree=0) (Figure 3-3).
    - KHOS showed acceptable internal consistency for both scales among individuals undergoing dental extraction [0.62 and 0.64] (van Wijk et al., 2010) and US adults [0.66 and 0.80] (Braman et al., 2004),
    - The sum scores of KHOS subscales were matched to ODIN-Q subscales.
    - Shapiro-Wilk normality test indicated a non-normal distribution of ODIN-Q scores ($P < .05$). Thus, the Spearman's correlation coefficient (two-tailed test of significance) was used to measure the magnitude of correlations between the scores of ODIN-Q and KHOS (Nease et al., 1995, Lopez-Jornet et al., 2012, Riffenburgh, 2012a).

Figure 3-3 The 16-item Krantz Health Opinion Survey.

Information subscale	*Q1. ‘I usually don’t ask the doctor or nurse many questions about what they are doing during a medical examination’;*
	Q3. I’d rather have doctors and nurses make the decisions about what’s best than for them to give me a whole lot of choices’.
	Q4. ‘instead of waiting for them to tell me, I usually ask the doctor or nurse immediately after an examination about my health’.
	Q8. ‘I usually ask the doctor or nurse lots of questions about the procedures during a medical examination’.
	Q10. ‘it is better to trust the doctor or nurse in charge of medical procedure than to question what they are doing’.
	Q15. ‘I usually wait for the doctor or the nurse to tell me the results of a medical examination rather than asking them immediately’
	Q16. ‘I’d rather be given many choices about what’s best for my health than to have the doctor make the decisions for me’.
Behavioural subscale	*Q2. 'Except for serious illness, it is generally better to take care of your own health than to seek professional help'*
	Q5. 'It is better to rely on the judgments of doctors (who are the experts) than to rely on “common sense” in taking care of your own body'
	Q6. 'Clinics and hospitals are good places to go for help since it is best for medical experts to take responsibility for health care'
	Q7. 'Learning how to cure some of your illness without contacting a physician is a good idea'
	Q9. 'It’s almost always better to seek professional help than to try to treat yourself'
	Q11. 'Learning how to cure some of your illness without contacting a physician may create more harm than good'
	Q12. 'Recovery is usually quicker under care of a doctor or a nurse than when patients take care of themselves'
	Q13. 'If it costs the same, I’d rather have a doctor or a nurse give me treatments than to do the same treatments myself'
	Q14. 'It is better to rely less on physicians and more on your own common sense when it comes to caring for your body'

Criterion validity reflects how accurate is an item score comparing with the gold standard of the same item (McDowell, 2006). The gold standard measure is however often not available (Bowling, 2014) or not yet exited for PROMs (e.g. ODIN-Q) except the longer form of the same PROM (Mokkink et al., 2010a, Mokkink et al., 2018b). Thus, it was not tested in the present study. However, a verification of this validity might be seen through performing factor analysis (Dale et al., 2004). Responsiveness was not measured in the present study as ODIN-Q was not primarily aimed to detect changes on the need for information overtime.

3.2.5. Ethical consideration and study registration

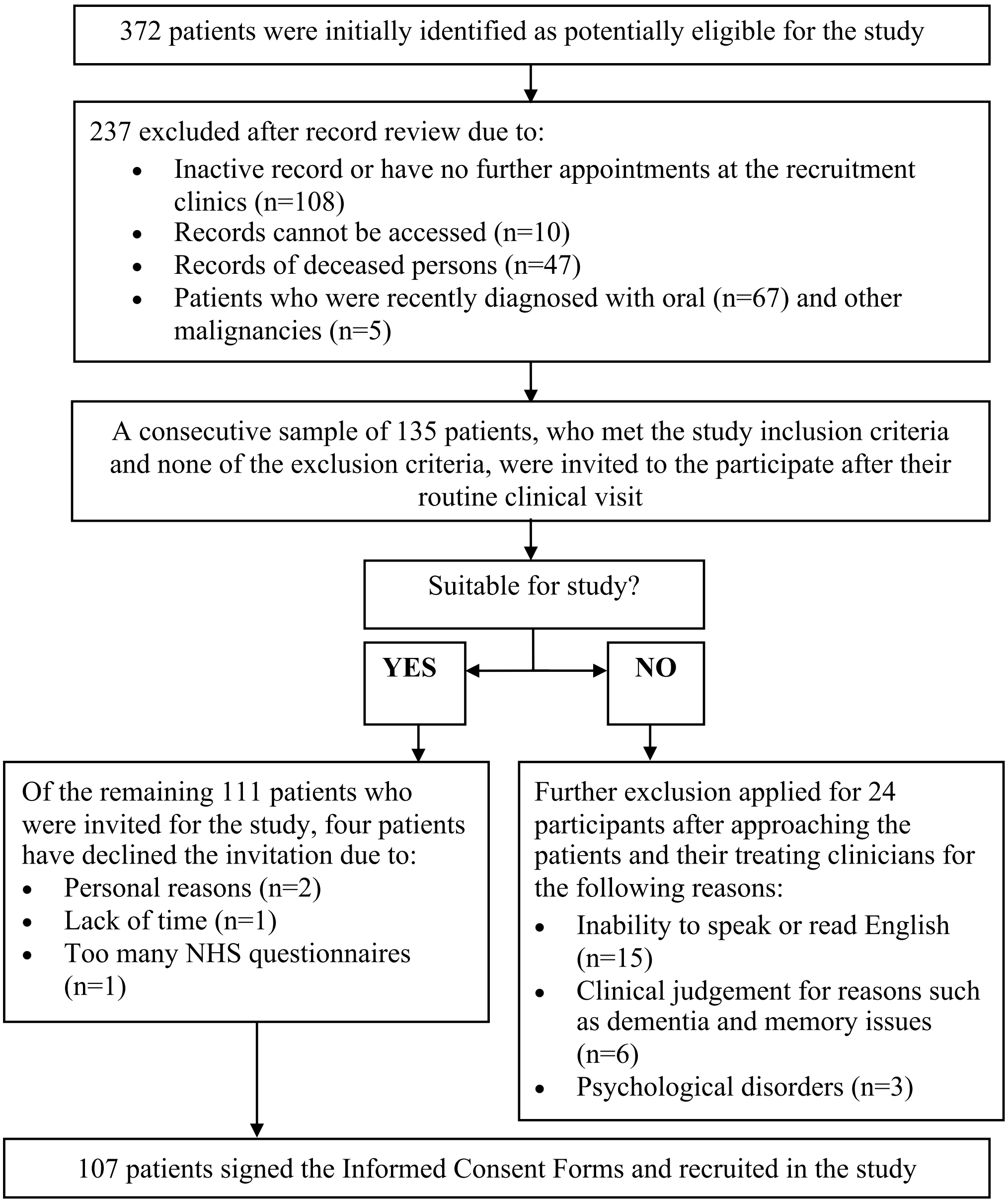
The study protocol was conducted in agreement with the Declaration of Helsinki for medical research including human subjects. An independent expert reviewed the protocol and supported the rigour and feasibility of the study. After the local registration of the study with UCLH/UCL Joint Research Office (JRO reference number: 18/0203, IRAS project ID: 242552), some changes were undertaken regarding the management of personal data in the Participant Information Sheet as per the recent General Data Protection Regulation for health and care research (NHS Health Research Authority, 2018), which was published after the initial submission for ethical review.

The study was subsequently reviewed and given a favourable opinion by NHS Health Research Authority, Research Ethics Committees (London – City & East Research Ethics Committee, reference, 18/LO/1340) on 6 August 2018 (https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/odin-q-information-needs-in-oral-epithelial-dysplasia-v10/) [Appendix 5]. The Participant Information Sheet, Informed Consent Forms and GP letters approved for the study are presented in Appendix 6.

The study was also recorded in the NIHR Central Portfolio Management System with the oral and dental health as a speciality and cancer as a supporting speciality (CPMS reference: 39323) and clinical trials registry maintained by the USA National Institutes of Health https://clinicaltrials.gov (reference, NCT04153266).

3.3. Results

Searches for UCLH electronic databases identified 372 patients as potentially eligible for the study. Steps performed from identifying the potentially eligible patients to recruitment are highlighted in Figure 3-4. The response rate for those who were invited for the study was 96% (107 out of 111 patients). All participants completed the Informed Consent Forms (Appendix 6) after their routine clinical visit on the same day or after their next visit.



372 patients were initially identified as potentially eligible for the study

237 excluded after record review due to:

- Inactive record or have no further appointments at the recruitment clinics (n=108)
- Records cannot be accessed (n=10)
- Records of deceased persons (n=47)
- Patients who were recently diagnosed with oral (n=67) and other malignancies (n=5)

A consecutive sample of 135 patients, who met the study inclusion criteria and none of the exclusion criteria, were invited to the participate after their routine clinical visit

Suitable for study?

YES

NO

Of the remaining 111 patients who were invited for the study, four patients have declined the invitation due to:

- Personal reasons (n=2)
- Lack of time (n=1)
- Too many NHS questionnaires (n=1)

Further exclusion applied for 24 participants after approaching the patients and their treating clinicians for the following reasons:

- Inability to speak or read English (n=15)
- Clinical judgement for reasons such as dementia and memory issues (n=6)
- Psychological disorders (n=3)

107 patients signed the Informed Consent Forms and recruited in the study

Figure 3-4 Steps performed to identify and recruit potentially eligible patients.

Of the 107 recruited participants, 4 were withdrawn from the study [two for personal reasons, one for language difficulty and one due to cardiac event and death at home] and 11 did not complete ODIN-Q. Thus, the final completion rate for ODIN-Q was at 84% (90 out of 107). After eliminating questionnaires with multiple missing responses (n=4), responses from 86 respondents were included for descriptive and validation analyses.

3.3.1. Demographic and clinical characteristics of the participants

A summary of the demographic and clinical characteristics for the 86 participants is shown in Appendix 7. The participants were 41 males and 45 females with 78% of them were white (British=50, Irish=1 and others=16) followed by 22% Asians or Asian British (Indians=7, Pakistani=4 and others=5). Two other participants were black or black British and one was mixed white and Asian. The mean and median age were at 65 years (31-89 years). Based on the 10-year age group, 39% belonged to the age group between 60-69 years (n=34), 26% to 70-79 (n=23), 17% to 50-59 (n=15), 8% to 80-89 (n=7), 4% to 40-49 (n=4) and 2% to 30-39 (n=2). Regarding educational levels, sixty-four percent of the 81 participants who provided information about their education had some college or higher education degree (Figure 3.5).

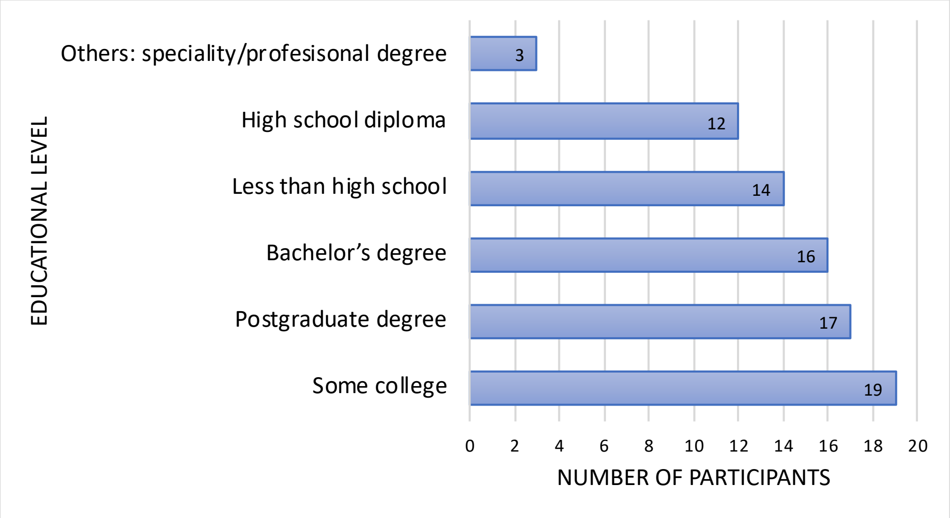


Figure 3-5 Educational levels of participants (n=81).

Regarding employment status, 51 out of 86 were retired, 15 employed fill-time, 11 self-employed, four unemployed, one employed part-time and five participants did not specify their status. 10% are currently smoking mostly cigarettes with a varied number of cigarettes per day from 1 to 10 (n=3) and 11 or more (n=5) and only one participant was a pipe smoker on daily basis. The remaining 90% was divided between past smoking or chewing of tobacco (56%) and never (34%). In contrast, 54 of the participants (63%) are currently consuming alcohol but not on a day-to-day basis (n=17), 1-2 units on a typical day (n=16), 3-4 units (n=10), 5-6 units (n=6) and more than 7 units (n=5). Furthermore, 25 participants reported never or rarely alcohol drinking and seven others were drinking in the past.

Reviews of the available clinical data and histopathological reports showed a total number of biopsies found to have OED for all participants of 143 (highest per person=13, lowest=1) and an average number of 1.67 for each participant. 44% of these biopsies, based on WHO grading for OED (El-Naggar et al., 2017), were graded as mild dysplasia (n=63), 19% mild to moderate (n=27), 13% moderate (n=19) and 6% moderate to severe OED (n=8). The remaining 18% were of severe OED (n=26) which however might have been skewed by the presence of ten HPV-associated (koilocytic) severe dysplasia in one participant (study identifier, 187). The number of lesions could not be determined as the records did not in some instances provide a clear understanding of lesion number versus site of biopsy.

111 sites were affected, representing 13 regions of the oral cavity (Figure 3.6). The tongue (lateral, ventral and dorsum regions) was the most affected site (46%) followed by the buccal mucosa (19%).

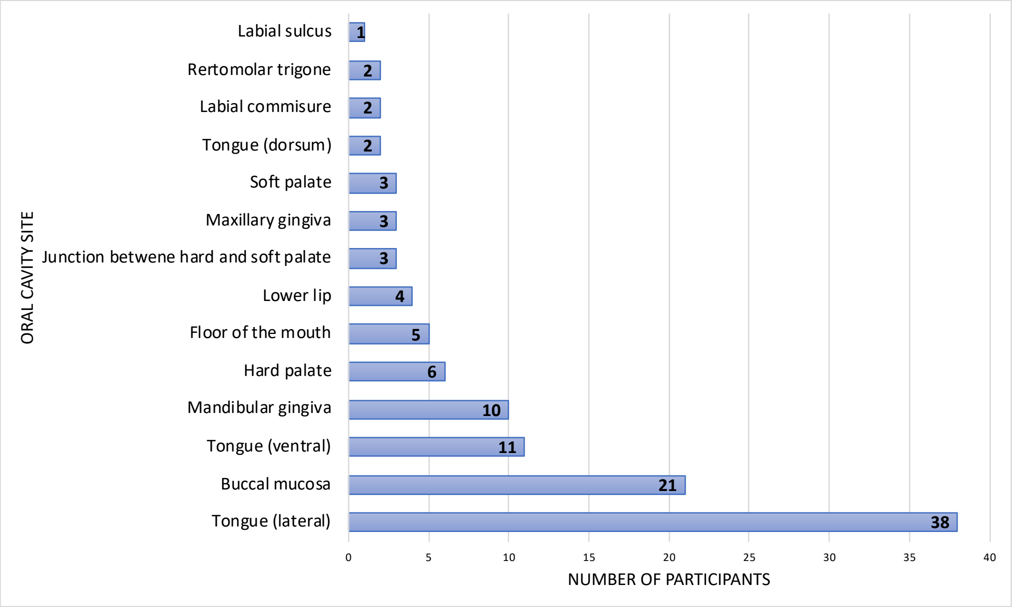


Figure 3-6 Oral cavity sites of OED involvement (n=103).

Further clinical information about the lesions (size of the lesion and number of interventions performed) and the dental health (decay-missing-filled index and periodontal health) of the participants could not be determined as many of these were not investigated or conducted in the hospital of the study or the units that may have referred patients.

All participants had clinical and/or histopathological evidence of one or more oral conditions that have been linked to OED based on the clinically or based on histopathology examinations. However, 22% of them had no recorded oral condition. Oral lichen planus/lichenoid reaction was present in 40% of the participants (n=35) followed by “oral leukoplakia” (n=9) and its verrucous subtype (n=7), oral candidosis (n=4) and its chronic hyperplastic form (n=4), oral submucous fibrosis (n=3), HPV-associated lesions (n=2) and “oral erythroplakia” (n=1). Other conditions which may however not be necessarily related to OED lesions were present such as immunosuppression therapy for renal transplant, mucous membrane pemphigoid (desquamative gingivitis) and dermatomyositis which affected one participant of each.

Six patients had a history of malignancy; cutaneous melanoma and basal cell carcinoma [study ID, 175], oral squamous cell carcinoma (OSCC) of the oral cavity (ventral tongue [176], buccal mucosa [184], lateral tongue [187] and floor of the mouth [195]); breast cancer [206] and oropharyngeal SCC [207].

Sixty-three participants (73%) had no current oral symptoms related to OED lesion and its associated conditions, 20 (23%) had intermittent soreness/pain and 2 (2%) with post-operative (biopsy/surgery) neuropathic pain. Moreover, the participants had an average of 3 ongoing general medical conditions or issues (highest=9, lowest =0) and an average number of medications of 3.5 for each participant (highest=15, lowest=0). However, these findings might be carefully interpreted due to the influence of clinician's style (e.g. some clinicians presented detailed medical history reviews whereas a few others did not), reasons for the recent visits (e.g. being recently seen for another oral or head and neck disease) and the number of consultations conducted.

3.3.2. Information needs concerning OED

The analyses for participants' responses for each item under both scales of ODIN-Q are shown in Table 3-7. For each item under both ODIN-Q subscales, answers highlighted with bold were the highest scored by the participants.

Table 3-7 Number and percentages of responses for each item of ODIN-Q.

Item No.	**Amount of information received/ degree of importance**					**Median (mean) score**
	Too much/ very important	Enough/ important	Not enough/ Not very	None/ Not Important	Not applicable	
1	0 (0%)/ **52 (60%)**	**72 (83%)/** 31 (36%)	11 (13%)/ 2 (2%)	3 (3%)/ 1 (1%)	0 (0%)/ 0 (0%)	3 (2.80)/ 4 (3.55)
2	0 (0%)/ 30 (35%)	**50 (58%)/** **42 (49%)**	18 (21%)/ 9 (10)	18 (21%)/ 5 (6%)	0 (0%)/ 0 (0%)	3 (2.37)/ 3 (3.12)*
3	0 (0%)/ **46 (53%)**	**64 (74%)/** 30 (35%)	13 (15%)/ 7 (8%)	9 (10%)/ 3 (3%)	0 (0%)/ 0 (0%)	3 (2.64)/ 4 (3.38)
4	0 (0%)/ **45 (52%)**	**73 (85%)/** 35 41%)	6 (7%)/ 4 (5%)	7 (8%)/ 2 (2%)	0 (0%)/ 0 (0%)	3 (2.76)/ 3 (3.43)
5	0 (0%)/ **41 (48%)**	**60 (70%)/** 40 (46%)	14 (16%)/ 3 (3%)	12 (14%)/ 2 (2%)	0 (0%)/ 0 (0%)	3 (2.55)/ 3 (3.39)
6	0 (0%)/ 24 (28%)	20 (23%)/ **40 (47%)**	14 (16%)/ 13 (15%)	**52 (60%)/** 9 (10%)	0 (0%)/ 0 (0%)	1 (1.62)/ 3 (2.91)*
7	1 (1%)/ **62 (72%)**	**60 (70%)/** 21 (24%)	18 (21%)/ 0 (0%)	7 (8%)/ 3 (3%)	0 (0%)/ 0 (0%)	3 (2.64)/ 4 (3.65)
8	2 (2%)/ **33 (38%)**	**50 (58%)/** 26 (30%)	5 (6%)/ 5 (6%)	12 (14%)/ 5 (6%)	17 (20%)/ 17 (20%)	3 (2.60)/ 3 (3.26)†
9	0 (0%)/ 25 (29%)	**44 (51%)** **29 (34%)**	8 (9%)/ 11 (13%)	19 (22%)/ 6 (7%)	15 (17%)/ 15 (17%)	3 (2.35)/ 3 (3.02)$^{\dagger *}$
10	1 (1%)/ **52 (60%)**	**55 (64%)/** 30 (35%)	20 (23%)/ 2 (2%)	10 (12%)/ 2 (2%)	0 (0%)/ 0 (0%)	3 (2.54)/ 4 (3.53)
11	0 (0%)/ **59 (69%)**	**68 (79%)/** 23 27%)	12 (14%)/ 3 (3%)	6 (7%)/ 1 (1%)	0 (0%)/ 0 (0%)	3 (2.72)/ 4 (3.62)
12	0 (0%)/ **31 (36%)**	16 (19%)/ 29 (34%)	21 (24%)/ 9 (10%)	**47 (54%)/** 15 (17%)	2 (2%)/ 2 (2%)	1 (1.63)/ 3 (2.90)$^{\dagger *}$
13	0 (0%)/ **44 (51%)**	**57 (66%)/** 34 (39%)	15 (17%)/ 7 (8%)	14 (16%)/ 1 (1%)	0 (0%)/ 0 (0%)	3 (2.50)/ 4 (3.40)
14	1 (1%)/ **56 (65%)**	**63 (73%)/** 27 (31%)	14 (16%)/ 2 (2%)	8 (9%)/ 1 (1%)	0 (0%)/ 0 (0%)	3 (2.66)/4 (3.60)
15	0 (0%)/ 54 (63%)	**66 (77%)/** 28 (32%)	13 (15%)/ 4 (5%)	7 (8%)/ 0 (0%)	0 (0%)/ 0 (0%)	3 (2.68)/ 4 (3.58)
16	0 (0%)/ **48 (56%)**	**57 (66%)/** 30 (35%)	13 (15%)/ 7 (8%)	16 (19%)/ 1 (1%)	0 (0%)/ 0 (0%)	3 (2.47)/ 4 (3.45)
17	1 (1%)/ **46 (53%)**	**64 (74%)/** 34 (40%)	10 (12%)/ 5 (6%)	11 (13%)/ 1 (1%)	0 (0%)/ 0 (0%)	3 (2.64)/ 4 (3.45)
18	0 (0%)/ 18 (21%)	16 (19%)/ **31 (36%)**	20 (23%)/ 22 (26%)	**50 (58%)/** 15 (17%)	0 (0%)/ 0 (0%)	1 (1.60)/ 3 (2.60)
19	0 (0%)/ **49 (57%)**	**53 (62%)/** 32 (37%)	15 (17%)/ 4 (5%)	18 (21%)/ 1 (1%)	0 (0%)/ 0 (0%)	3 (2.40)/ 4 (3.50)*

20	0 (0%)/ **52 (60%)**	**59 (69%)/** 30 (35%)	17 (20%)/ 2 (2%)	10 (12%)/ 2 (2%)	0 (0%)/ 0 (0%)	3 (2.57)/ 4 (3.53)
21	0 (0%)/ **41 (48%)**	**40 (47%)/** 37 (43%)	21 (24%)/ 4 (5%)	25 (29%)/ 4 (5%)	0 (0%)/ 0 (0%)	2 (2.17)/ 3 (3.33)*
22	0 (0%)/ **47 (55%)**	**51 (60%)/** 32 (37%)	16 (19%)/ 4 (5%)	29 (22%)/ 3 (3%)	0 (0%)/ 0 (0%)	3 (2.37)/ 4 (3.43)*
23	0 (0%)/ 37 (43%)	**37 (43%)/** **40 (46%)**	22 (26%)/ 6 (7%)	27 (31%)/ 3 (3%)	0 (0%)/ 0 (0%)	2 (2.11)/ 3 (3.29)*
24	1 (1%)/ **62 (72%)**	**58 (67%)/** 22 (26%)	15 (17%)/ 1 (1%)	12 (14%)/ 1 (1%)	0 (0%)/ 0 (0%)	3 (2.55)/ 4 (3.68)
25	0 (0%)/ **50 (58%)**	**54 (63%)/** 30 (35%)	16 (19%)/ 5 (6%)	16 (19%)/ 1 (1%)	0 (0%)/ 0 (0%)	3 (2.44)/ 4 (3.50)*
26	0 (0%)/ 33 (39%)	**39 (45%)/** **34 (40%)**	14 (16%)/ 14 (16%)	33 (38%)/ 5 (6%)	0 (0%)/ 0 (0%)	2 (2.07)/ 4 (3.10)*
27	0 (0%)/ 8 (9%)	16 (19%)/ 15 (17%)	6 (7%)/ 9 (10%)	15 (17%)/ 5 (6%)	**49 (57%)/** **49 (57%)**	0 (2.02)/0 (2.70)†*
28	0 (0%)/ **43 (50%)**	**74 (86%)/** 37 (43%)	5 (6%)/ 4 (5%)	7 (9%)/ 2 (2%)	0 (0%)/ 0 (0%)	3 (2.77)/ 3.5 (3.40)
29	0 (0%)/ 24 (28%)	35 (41%)/ **30 (35%)**	13 (15%)/ 19 (22%)	**38 (44%)/** 13 (15%)	0 (0%)/ 0 (0%)	2 (1.96)/ 3 (2.75)*
30	0 (0%)/ **48 (56%)**	**64 (74%)/** 30 (35%)	6 (7%)/ 6 (7%)	16 (19%)/ 2 (2%)	0 (0%)/ 0 (0%)	3 (2.55)/ 4 (3.44)
31	1 (1%)/ 25 (29%)	24 (28%)/ **31 (36%)**	13 (15%)/ 20 (23%)	**48 (56%)/** 10 (11%)	0 (0%)/ 0 (0%)	1 (1.74)/ 3 (2.82)*
32	0 (0%)/ 13 (15%)	14 (16%)/ 17 (20%)	11 (13%)/ **29 (34%)**	**61 (71%)/** 27 (31%)	0 (0%)/ 0 (0%)	1 (1.45)/ 2 (2.18)±
33	0 (0%)/ 17 (20%)	32 (37%)/ **38 (44%)**	14 (16%)/ 20 (23%)	**40 (47%)/** 11 (13%)	0 (0%)/ 0 (0%)	2 (1.90)/ 3 (2.70)*
34	0 (0%)/ 30 (35%)	**55 (64%)/** **36 (42%)**	7 (8%)/ 8 (9%)	21 (24%)/ 9 (10%)	2 (2%)/ 3 (3%)	3 (2.42)/ 3 (3.04)†*
35	0 (0%)/ 24 (28%)	**40 (46%)/** **38 (44%)**	14 (16%)/ 17 (20%)	32 (37%)/ 7 (8%)	0 (0%)/ 0 (0%)	2 (2.09)/ 3 (2.91)*

†Mean scores were calculated after omitting not applicable responses for item 8, 9, 12, 27 and 34.

*****The information was not enough on the item (at least among 20% of the respondents) and it is considered important by the participants.

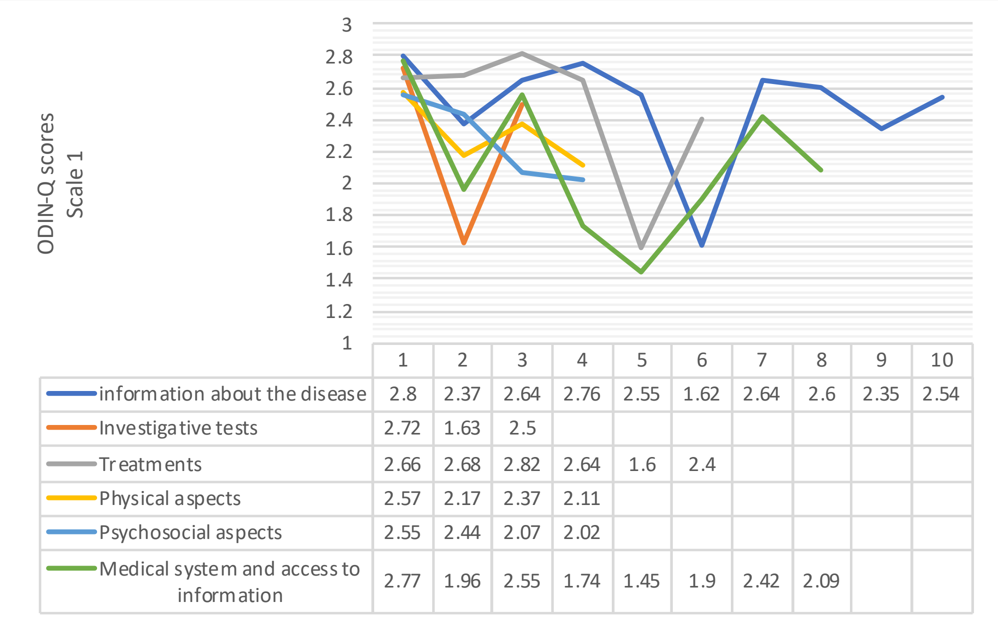
±There was unmet IN on the item however it was not important.

i. Amount of information received subscale (ODIN-Q)

Which domains and items with high unmet information needs?

As indicated in Table 3-7, the mean and median total scores for all items in subscale 1 (amount of information received) were at 2.33 (± 0.38) and 2.44 which indicated an overall unmet IN about OED among the present study sample for the six domains. Items under the medical system and access to information domain obtained the lowest mean and median scores (2.11/2.02) followed by psychosocial aspects of OED (2.27/2.25) and physical aspects of OED (2.30/2.27). In contrast, the highest scored domains achieved scores marginally above the 50th percentile value of total score for all domains (2.44); information about treatments for OED (2.47/2.65), information about the disease (2.49/2.57) and information about investigative tests of OED (2.28/2.50).

Figure 3-7 shows the mean scores of items under each domain of ODIN-Q (subscale 1). None of these items was scored as ‘enough’ with the highest and lowest scores at 2.80 and 1.45 out of 4, respectively.



	1	2	3	4	5	6	7	8	9	10
information about the disease	2.8	2.37	2.64	2.76	2.55	1.62	2.64	2.6	2.35	2.54
Investigative tests	2.72	1.63	2.5							
Treatments	2.66	2.68	2.82	2.64	1.6	2.4				
Physical aspects	2.57	2.17	2.37	2.11						
Psychosocial aspects	2.55	2.44	2.07	2.02						
Medical system and access to information	2.77	1.96	2.55	1.74	1.45	1.9	2.42	2.09		

Figure 3-7 Line representation of the mean scores for all items in scale 1 (n=35).

Based on the analyses of mean scores for individual items (Table 3-7), the 35 items of subscale 1 of ODIN-Q (amount of information received OED) were regarded as 10 highly unmet (29%), 14 somewhat met (40%) and 9 often met items (26%). The remaining two items (5%) about community/patient support groups (Q32) and complementary and alternative medicine (Q18) were highly unmet however both considered not important by 65% and 43% of the 86 participants, respectively.

Regarding items with high unmet IN based on the mean and median scores, 66 participants (76%) noted having not enough/no information on the role of human papilloma virus (Q6), 68 (78%) on genetic testing and chance of inheritance to children (Q12), 61 (71%) on psychological support and advice (Q31), 54 (61%) on health promotion (Q33), 51 (59%) on seeking another professional opinion (Q29), 47 (54%) on how the disease/treatment may affect social life (Q26), 46 (53%) on the research and recruitment for clinical trials (Q35), 49 (57%) on the diet and nutrition (Q23) as well as 46 participants (53%) on the chances of spreading to an adjacent or distant body part (Q21). Also, 21 (56%) out of 37 participants who found how the disease/treatment may affect their job/career (Q27) applicable to them noted unmet IN about this item.

Despite its median scores at or above 3 out of 4, Items with met IN among more than 50% of participants included the following: how frequent and severe are the symptoms (Q20), whether it is contagious or not (Q5), how to obtain physical support and advice (Q30), about the fear of progression to cancer (Q24), what is likely to happen to OED in the future (Q10), benefits, risks, how each test works, and the meaning of test results (Q13), how disease/treatment affects the quality of life (Q16), how to cope with the possible effects of the disease/treatment (Q25), lifestyle adjustment (Q34), the chances of a cure (Q19), the effects of the disease/treatment on daily physical activities (Q22), how common is OED (Q2), what will happen if I continue to smoke or drink alcohol (Q8) and what is a safe level of alcohol to drink (Q9).

Items which were considered as highly met (mean = >2.60 out of 4) included what oral epithelial dysplasia (OED) is (Q1), the experience of the doctor and other health care staff (Q28), how it looks in the mouth or lips (Q4), screening and early detection (Q11), benefits, risks, and how each treatment works (Q15), what will happen if it is not treated (Q14), risk factors for developing it (Q3), disease grades and risk of developing mouth cancer (Q7), the self-management at home (Q17), respectively.

A few participants noted that there was too much information on some items related to what will happen if one continue smoking/alcohol drinking (Q8, n=2), OED grades and the risk of developing cancer (Q7, n=1), what will happen to OED in the future (Q10, n=1) and if it is not treated (Q14, n=1), self-management at home (Q17, n=1), fear of progression to cancer (Q24, n=1) and how to obtain psychological support and advice (Q31, n=1).

Some participants considered specific items not applicable to themselves. For example, those who do not smoke and/or drink reported items linked to these habits as not applicable in response to question 8 (n=17), 9 (n=15) and 34 (n=2). Also, participants who were retired noted similar responses to question 27 about how disease/treatment affects their job (n=49).

Based on the pre-defined cut-off level developed for the total ODIN-Q score (Table 3.5), the analyses showed that no respondent indicated having too much information received on most items whereas around half of the participants (n=41) had enough information on most items. Nevertheless, the remaining 45 respondents (52%) noted having unmet IN either by receiving insufficient information (n=37) or no information on most items of ODIN-Q (n=8) (Figure 3-8)

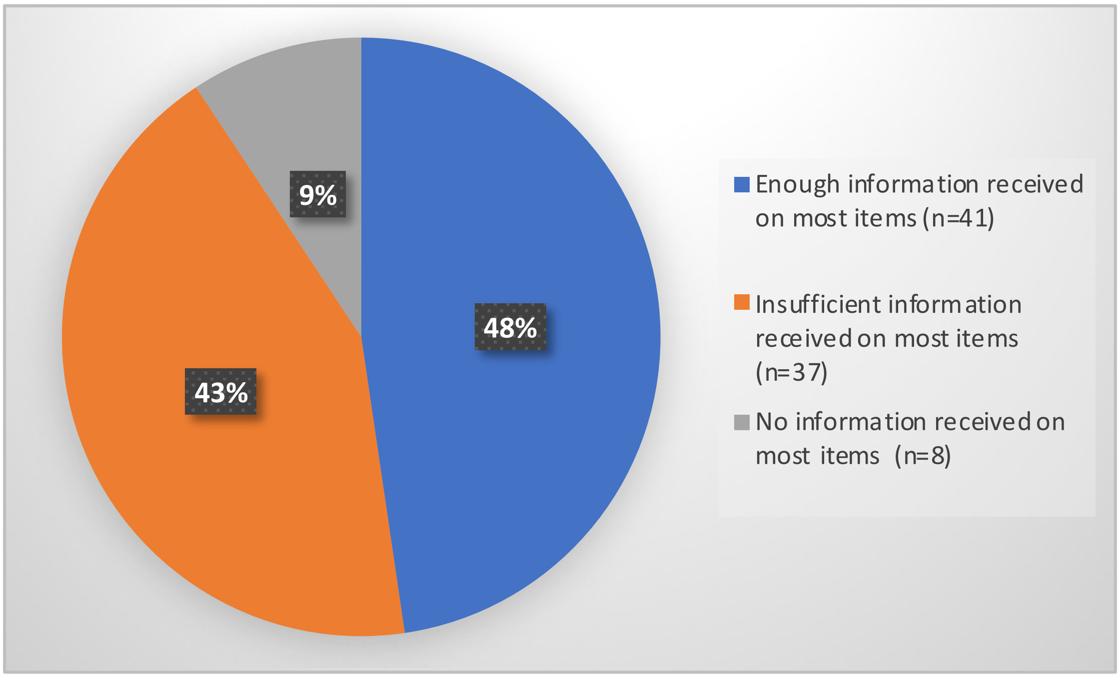


Figure 3-8 Interpretations for the total scores of subscale 1 of ODIN-Q (n=86)

The demographic characteristics for individuals with unmet needs were similar to the study group regarding the mean age (for this group and the study populations of 65 years old), gender (64% and 62% were females, respectively), ethnic group (69% and 78% were White), education (58% and 64% had some college or higher education degree), employment status (49% and 59% were retired), smoking status (55% and 56% were past tobacco smokers or chewers) and alcohol drinking (58% and 63% were currently drinking).

The descriptive analyses showed similarities between those who had unmet needs and other participants in the study with clinical variables such as degree of OED (53% and 44% were of mild OED), the associated oral conditions (44% and 40% had a diagnosis of OLP/lichenoid reaction) and the tongue as the most affected site (49% versus 46%). Nevertheless, this group had a lower number of OED lesions for each participant compared with the study population (1.2 versus 1.67) as well as a higher number of ongoing general medical conditions or issues (3.7 versus 3 for each participant) and the number of medications (4.1 versus 3.5). These differences were greater for oral symptoms related to OED or its associated oral condition at the most recent clinical visit (40% versus 25% of both groups were symptomatic). Also, this group included 3 of the 6 participants who had malignancies in the past especially in the last seven years (oropharyngeal SCC, 2016 [participant 207]; breast cancer, 2012 [participant 206] and cutaneous SCC, 2012 [participant 175]).

As Shapiro-Wilk test indicated a non-normal distribution of ODIN-Q scores ($P < .05$), thus, Spearman's correlation coefficient indicated a negative correlation between the score of the amount of information received scale (ODIN-Q) and both the number of current medical conditions ($r = -.389$, $p = .000$) and the number of current medications ($r = -.394$, $p = .000$). However, these were considered as negligible based on Guilford's interpretation.

When the demographics and clinical variables were tested with regression models, the amount of information received score was significantly related to the number of medications ($p < .05$). The score was decreased by 1.51 for every additional medication ($t = -.326$, 95% CI [-2.46 - -.55]) – as shown by the linear regression analyses. Whereas the category of amount of information received (met or unmet IN) was significantly predicted by the gender ($p < .05$) as found with the binary logistic regression (Wald test forward method). This test indicated that males were 65% less likely to report 'not enough' information about OED than females (OR= 0.35, 95% CI [0.14-0.86]) with a statistical significance level (p value) at 0.022.

ii. Degree of importance subsscale (ODIN-Q)

Similar to the analyses of total participants' scores for scale 1, these scores were adjusted for not applicable responses (i.e. deducting 4 points for each not applicable response). In summary, 81 of the 86 participants (94%) viewed most of ODIN-Q items as important, with five respondents considered some or many items as unimportant (Figure 3-9).

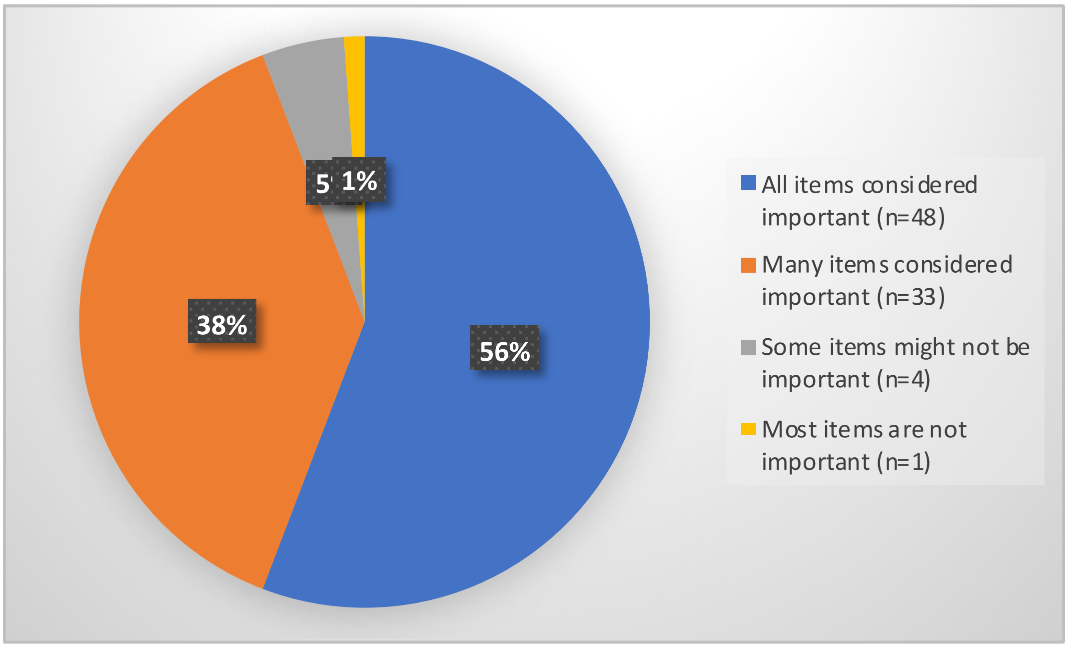
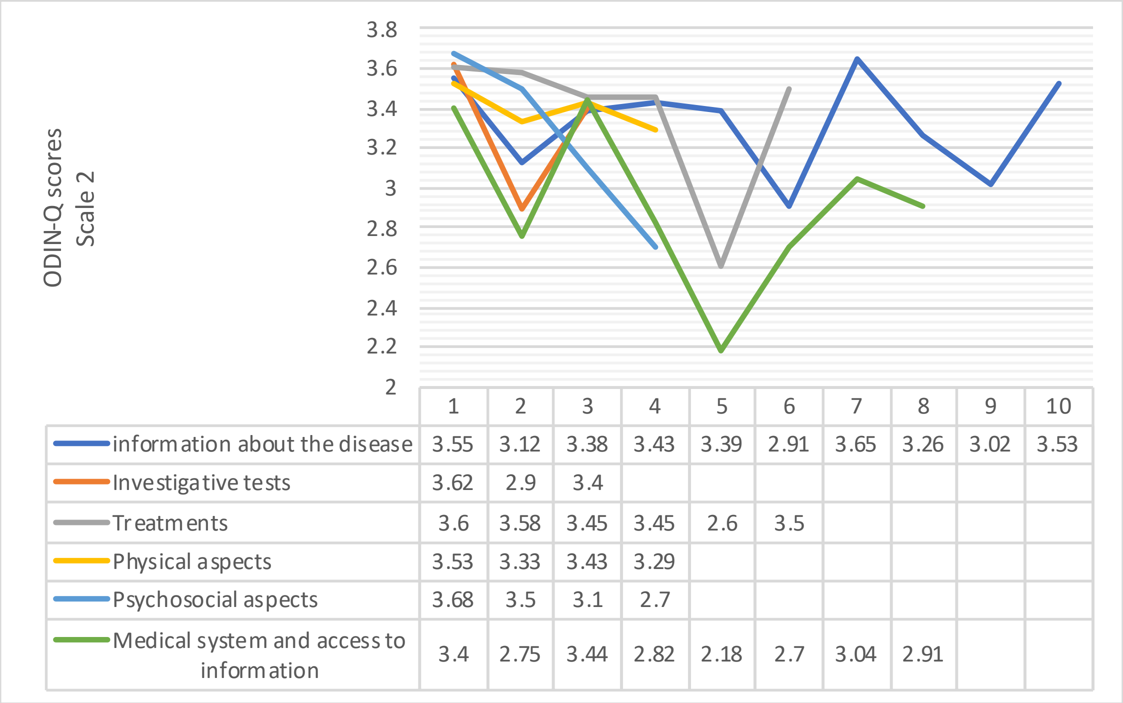


Figure 3-9 Interpretations for the total scores for scale 2 of ODIN-Q (n=86).

Which domains and items were considered important?

The analyses for scale 2 of ODIN-Q (degree of importance) showed that 33 out of the 35 items and six domains of ODIN-Q were regarded as important with overall mean and median of scores at 3.23 (±0.36) and 3.39 out of 4, respectively. Domains with high importance mean scores were physical aspects of OED (3.39), treatments (3.36), information about the disease (3.32), investigative tests (3.30) and psychosocial aspects (3.24). The medical system and access to information domain was to some extent of less importance with an average score of 2.89. In contrast, all domains were considered important, with median scores lies between 3.30 and 3,47, except the psychosocial domain (2.86).

Unlike the responses for the first scale, the scores for importance scale were moderately agreed between participants who provided high mean (Figure 3.10) and median scores. An exception for this agreement was seen with two items obtaining low mean and median scores: community/patient support groups (Q32) and the disease/treatment on the job/career (Q27). These items were considered not important and not important/not applicable by 65% and 73% most of the participants, respectively.



	1	2	3	4	5	6	7	8	9	10
information about the disease	3.55	3.12	3.38	3.43	3.39	2.91	3.65	3.26	3.02	3.53
Investigative tests	3.62	2.9	3.4							
Treatments	3.6	3.58	3.45	3.45	2.6	3.5				
Physical aspects	3.53	3.33	3.43	3.29						
Psychosocial aspects	3.68	3.5	3.1	2.7						
Medical system and access to information	3.4	2.75	3.44	2.82	2.18	2.7	3.04	2.91		

Figure 3-10 Line representation of the mean scores for all items in scale 2 (n=35).

The highest important items for nearly all of the participants (≥96%) were about the fear of progression to cancer (Q24), disease grades and risk of developing mouth cancer (Q7), the screening and early detection (Q11) and what will happen if it is not treated (Q14). By analysing both scales of ODIN-Q, 14 items were important and insufficiently addressed (Figure 3-11).

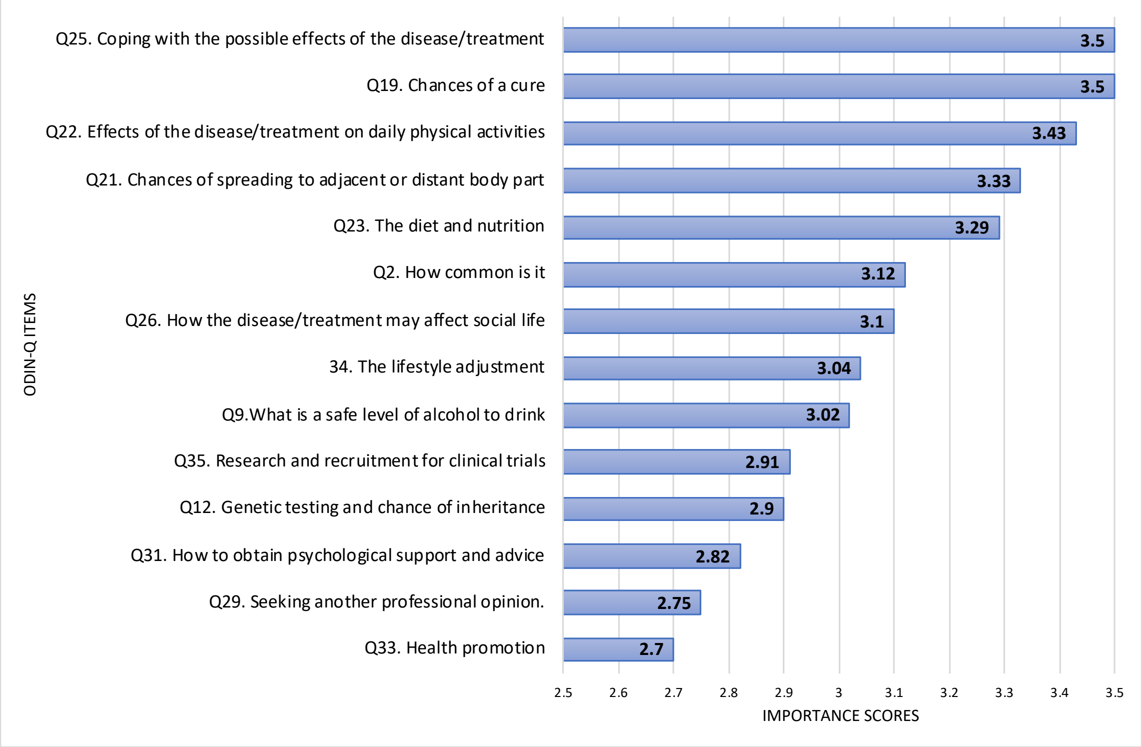


Figure 3-11 Important items viewed by the participants as insufficiently discussed (n=14).

Preferred sources of information about OED

95% of the 86 participants opted for one or more choices as their preferred sources of information about OED (Table 3-8). The highest selected choice was one-to-one meeting (76%) with OED specialists such as those in oral medicine, oral surgery, or ENT specialities (n=53), general dental practitioner (n=32), general practitioner (n=27) and auxiliary medical staff such as medical or dental nurses (n=26). Based on the ranking of the primary choice among these professionals, 90% of respondents ranked OED specialists as their first, 6% for the general dental practitioner, 4% for the general practitioner and none has chosen the auxiliary medical staff as their first.

Furthermore, highly chosen sources included printed information materials such as pamphlets, books, magazines, newspapers (53%) and the Internet (35%). On the contrary, four participants did not indicate a preference for any of these sources.

Table 3-8 Preferred sources to receive information about OED.

Source of information	**Number of participants who chose this modality (%)**
One-to-one meeting	58 (76%)
General dental practitioner	*32 (37%)*
General practitioner	*27 (31%)*
OED specialists	*53 (61%)*
Auxiliary medical staff	*26 (36%)*
Walk-in help centre	17 (20%)
Group information session	13 (15%)
Printed information materials	46 (53%)
World Wide Web	30 (35%)
TV/radio	8 (9%)
DVD/audio recording	4 (5%)
No choice	4 (5%)

What else the patients with OED wanted to know?

The responses to the open-ended question at the end of ODIN-Q (*please indicate other topics not included in the list*) included suggestions for further topics to be considered or discussed with the clinical care team and personal experiences related to the disease or its management.

Participants highlighted the need for (1) sharing care information with other patients, ***‘would be helpful to be able to share anecdotally treatment options, outcomes with similarly diagnosed patients’*** (participant 108); (2) considering further information about surgery for OED lesions, **‘*recovery/healing post surgery information, how many stitches, how long before they disappear, pain/duration and severity after surgery, and advice on suitable diet*’** (participant 136) and (3) adding specific items to ODIN-Q, **‘*would photo's/illustrations improve understanding of OED and did information about OED derive mainly from a) written material given to you; b) internet search; or c) what you were told by medical staff at the clinic’*** (participant 143).

In contrast, other participants thought the items are adequate, **‘*very comprehensive list indeed*’** (participant 145) or nevertheless not applicable to their conditions, **‘*many of the questions not applicable in my case, as my problem remained dormant since being diagnosed and therefore discussion of treatment is un-necessary. My periodic visits are essential for my own assurance’*** (participant 146) and ***‘I am closely monitored for OED and have been stable for several years so many of these questions were difficult to answer and did not seem altogether relevant’*** (participant 150).

Other comments related to the experiences with OED and its management noted (1) the disagreement between different hospitals as toward managing OED lesions, ***‘referrals from [named hospital, A] to [named hospital, B] not hearing the same message i.e. [A] say urgent excision, [B] say non urgent.’*** (participant 122); (2) the feeling of exhaustion due to the disease and its treatment, ***‘I feel I have***

been hooked after very well at all strives with treatment/checks etc.' (participant 131) and (3) the personal experience on what it has been told, '***essentially I was told there was no definitive cause + no definitive treatment or prognosis. The OED might disappear as mysteriously as it came, or it might become cancerous. It should be kept much frequent regular observations + if it shows signs of getting worse, the only option was surgical excision. When it gets worse, I was warned that my tongue might permanently lose feelings + the OED might return - neither has happened (yet!)'*** (participant 156).

Furthermore, one participant (168) indicated a little knowledge to the topics presented throughout ODIN-Q such as what OED is, ***'(1) none of the medical staff have explained the definition of these words; (2) I am told about the importance of regular monitoring, but never any detail of why or how it may differ for each individual; (3) I have some general knowledge of most of these topics, but none or very little received or offered at Eastman; (4) these words (what OED is) have never been explained to me', how does it look like in the mouth 'never been shown any of the many photographs taken of my mouth (response to how it looks in the mouth), information about alcohol drinking and diet not specific to this condition (what is a safe level of alcohol to drink), (4) I apply common sense and eat sensitively (about the diet and nutrition) as well as the other items of ODIN-Q. For nearly all of these questions + topics, I have quietly considered them over the years since starting at Eastman, but never raised any of them explicitly with the doctors I have seen'.***

The former participant also felt he had little information about OED after completing the study questionnaire despite receiving detailed information previously, ***‘whilst medical assessments and treatments received at Eastman has been explained, completing the questionnaire has altered me to the fact that I know very little about OED. Each appointment at Eastman is focussed on a thorough assessments of my condition including many questions but I now realise little information is systematically offered to me’.***

3.3.3. Psychometric properties of ODIN-Q (reliability and validity)

i. Reliability

Internal consistency

The estimates of correlations between all items of ODIN-Q by Cronbach’s α showed excellent internal consistency for items under the amount of information received subscale (0.92), degree of importance subscale (0.94) and overall subscales and domains of ODIN-Q (0.92) (Table 3-9). Similarly, the analyses of domains showed high consistency on treatments (0.84 and 0.85), physical aspects (0.75 and 0.84), medical system and access to information (0.78 and 0.83) and information about the disease (0.74 and 0.83) domains.

In contrast, two domains were with questionable consistency: investigative tests (0.54 and 0.69) and psychosocial aspects (0.60 and 0.58). This might be due to the different responses between completions on item 12 (*the genetic testing and chance of inheritance to children (if applicable)* and item 27 (*how the disease/treatment may affect my job/career?*) for the former and latter domains, respectively.

Table 3-9 Internal consistency of domains and subscales of ODIN-Q

ODIN-Q Domain	**Number of items**	**Cronbach's coefficient**	
		Amount of information received subscale	Degree of importance subscale
Information about the disease	10	.74	.84
Investigative tests	3	.54 (.62) [a]	.69 (.81) [a]
Treatments	6	.84	.85
Physical aspects	4	.75	.84
Psychosocial aspects	4	.60 (.79) [b]	.58 (.75) [b]
Medical system and access to information	8	.78	.83
All domains combined	35	.92 (.93) [c]	.94 (.95) [c]

[a] After eliminating item 12 '*the genetic testing and chance of inheritance to children*' from the analysis.

[b] After eliminating item 27 '*how the disease/treatment may affect my job/career?'* from the analysis.

[c] The Cronbach's α scores after omitting item 12 and 27 from the analyses.

Test-retest reliability

The analyses of agreement between the first and second completion of ODIN-Q (test-retest) showed fair ratings of weighted kappa's coefficients for both subscales of ODIN-Q (0.53 for the amount of information received and 0.49 for the degree of importance, respectively).

Similarly, all domains under both subscales were rated as fair; information about the disease (0.50 and 0.49), investigative tests (0.45 and 0.41), treatments (0.55 and 0.52), physical aspects (0.53 and 0.48), psychosocial aspects (0.61 and 0.43) and medical system and access to information (0.55 and 0.53). Values for individual items are presented in Table 3-10.

Table 3-10 Reliability coefficients for the 35 ODIN-Q items.

Domain	ODIN-Q item	Weighted kappa coefficient	
		Amount of information received subscale	*Degree of importance subscale*
Information about the disease	What OED is?	0.64	0.53
	How common is it?	0.50	0.38
	Risk factors	0.39	0.29
	How it looks in the mouth or lips?	0.28	0.48
	Whether it is contagious or not?	0.69	0.63
	The role of human papilloma virus.	0.46	0.49
	Disease grades and risk of developing mouth cancer.	0.56	0.48
	What will happen if continues to smoke or drink alcohol?	0.56	0.59
	What is a safe level of alcohol to drink?	0.35	0.41
	What is likely to happen to OED in the future?	0.57	0.59
Investigative tests	The screening and early detection.	0.44	0.33
	The genetic testing and chance of inheritance to children.	0.29	0.45
	Benefits, risks, how each test works, and the meaning of test results.	0.62	0.44
Treatments	What will happen if it is not treated?	0.42	0.61
	Treatment options, benefits, risks, and how each treatment works.	0.55	0.52
	How the disease/treatment affects the quality of life.	0.55	0.42
	Self-management at home.	0.65	0.46
	Complementary and alternative medicine.	0.51	0.54
	Chances of a cure.	0.60	0.54
Physical	How frequent and severe are the symptoms?	0.40	0.40
	Chances of spreading to an adjacent or distant body part.	0.43	0.48
	How the disease/treatment affects daily physical activities.	0.63	0.39
	Diet and nutrition.	0.62	0.64
Psychosocial	Fear of progression to cancer.	0.66	0.20
	Coping with the possible effects of the disease/treatment.	0.65	0.42
	How the disease/treatment affects social life.	0.60	0.51
	How the disease/treatment affects job/career.	0.50	0.59

Medical system and access to information	The experience of the doctor and other health care staff.	0.33	0.54
	Seeking another professional opinion.	0.41	0.43
	Physical support and advice.	0.47	0.55
	Psychological support and advice.	0.54	0.44
	Community/patient support groups.	0.49	0.53
	Health promotion (e.g. promoting one's health literacy).	0.73	0.57
	The lifestyle adjustment	0.62	0.58
	Research and recruitment for clinical trials.	0.76	0.54

ii. Validity

Structural validity

The Kaiser-Meyer-Olkin Measure of Sampling Adequacy overall score for ODIN-Q was 0.524 and therefore indicated the adequacy of data for EFA (amount of information received, 0.74 and degree of importance, 0.86). Both subscales were statistically significant with Bartlett's Test of Sphericity (*p*=0.00) and approximate Chi-square values at 5374.568 which confirmed existing correlations between the items of ODIN-Q.

EFA analysis for the 35 items identified 17 components with eigenvalues higher than 1.0. To reduce the error variance and obtain meaningful factors, these were summarised to four factors for both scales. This was also supported by a scree plot which shows four curves where the number of components shows a clear transition of variance (visual elbow) (Hair et al., 1998, Revelle, 2009, Ruscio et al., 2012) (Figure 3.12).

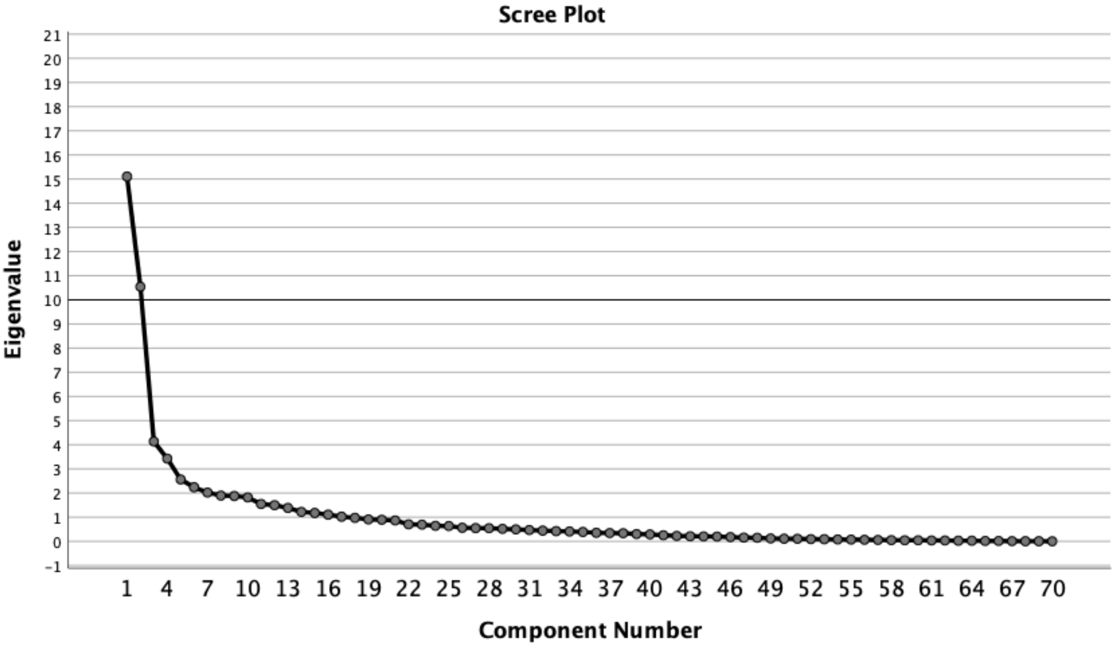


Figure 3-12 The scree plot for components (factors) with eigenvalues higher than 1.0 (n=17).

These four factors explained a cumulative variance loading at 47% of the variance (i.e. these factors explain 47% of the variance among the items). EFA analyses with principal component and varimax with Kaiser normalization as extraction and rotation methods showed 32 items with factor loadings above 0.40 in both scales (Table 3-11).

Nevertheless, three items showed low values in one of the subscales and however high in the other: the role of human papilloma virus (item 6), the genetic testing and chance of inheritance to children (item 12) and how the disease/treatment affects the job/career (item 27). Therefore, the latter two items were omitted from the final questionnaire which was also supported by the low internal consistency shown by Cronbach's α in addition to clinical judgement and relevance of these items to clinical care of patients with OED.

Table 3-11 Exploratory factor analyses for both scales of ODIN-Q.

Item	Component				Item	Component			
	1	2	3	4		1	2	3	4
1	.298	**.460**	.124	-.400	19	**.561**	-.101	.280	.249
	.844	.119	.008	-.208		-.142	**.737**	.031	-.113
2	.125	**.495**	-.001	-.133	20	**.765**	.048	-.117	.057
	.542	.083	.186	.039		-.102	**.582**	-.202	-.054
3	.271	**.525**	.031	-.303	21	**.781**	.076	-.148	-.073
	.782	.008	.028	-.082		.050	**.549**	.189	.216
4	.037	.430	.256	-.417	22	**.666**	-.112	.128	.026
	.784	-.007	.116	.090		.060	**.753**	-.054	.013
5	.139	**.458**	-.055	-.015	23	**.696**	.056	-.035	.173
	.584	-.098	.130	-.016		.004	**.658**	.032	.156
6*	.156	.345	.150	.076	24	**.658**	.040	.088	.356
	.559	-.123	-.020	.220		-.031	**.653**	.075	-.191
7	.080	**.501**	.225	-.418	25	**.689**	-.017	-.141	-.159
	.741	-.055	-.002	-.222		.034	**.766**	.053	-.142
8	.046	.124	**.812**	-.033	26	**.756**	.055	-.097	.182
	.266	.027	**.787**	.076		-.070	**.649**	.166	.178
9	-.034	.149	**.773**	-.052	*27*†*	***.639***	*-.039*	*.183*	*.419*
	.187	-.034	**.737**	.127		*-.102*	*.003*	*.258*	*.386*
10	-.132	**.449**	.029	-.428	28	.071	-.041	.271	**.454**
	.680	.030	-.050	-.255		-.073	**.463**	.021	-.258
11	.067	**.464**	.306	-.302	29	**.459**	.147	-.029	.115
	.792	-.007	.045	-.084		-.192	**.614**	-.044	.194
12†*	*.178*	*.398*	*.301*	*.232*	30*	.177	.064	-.052	.562
	.517	*-.031*	*.131*	*.249*		.229	**.555**	-.008	-.040
13	-.035	**.593**	.324	-.146	31	**.471**	.121	.055	-.029
	.702	.036	.143	.109		.017	**.671**	-.022	.333
14	.012	**.633**	.143	-.214	32	**.622**	-.045	.239	.526
	.787	.031	-.054	-.116		.032	**.549**	-.142	.402
15	-.038	**.706**	.048	-.180	33	**.415**	.009	-.119	.471
	.585	.105	.110	.030		.070	**.658**	.075	.283
16	-.129	.254	.265	.031	34	.558	.004	.169	**.466**
	.769	.136	-.069	.112		.092	**.484**	.383	-.111
17	.183	**.635**	-.153	-.126	35	.537	.091	**.544**	.051
	.788	.107	.062	-.001		-.198	**.429**	.343	.075
18	-.010	**.491**	.026	.243					
	.298	**.460**	.124	-.400					

*Low component loading (<0.40) on one scale.
†Deleted items from the final questionnaire.

Regarding the correlations between items and the extracted 4 factors, a few items presented high loadings to 2 factors and therefore were allocated to the one with the highest sum score on both scales of ODIN-Q (Hair et al., 1998). These factors were named based on the covered topics:

- Basic information about the disease (what OED is [1] how common is it [2], risk factors [3], how it looks in the mouth or lips [4], whether it is contagious or not [5], the role of human papilloma virus. [6], disease grades and risk of developing mouth cancer [7], the screening and early detection [11], benefits, risks, how each test works, and the meaning of test results [13], what will happen if it is not treated [14], how the disease/treatment affects each of the quality of life [16], physical activities [22] and social life [26], self-management at home [17], how frequent and severe are the symptoms [20], chances of spreading to adjacent or distant body part [21], fear of progression to cancer [24], coping with the possible effects of the disease/treatment [25] and lifestyle adjustment [34]).
- Disease management and professional support (what is likely to happen to OED in the future [10], treatment options and how each treatment works [15], complementary and alternative medicine [18], chances of a cure [19], the diet and nutrition [23], the experience of the doctor and other health care staff [28], seeking another professional opinion [29], physical support and advice [30] and psychological support and advice [31]).
- Access to information and future opportunities (what will happen if continues to smoke or drink alcohol [8], what is a safe level of alcohol to drink [9], research and recruitment for clinical trials [35]).

- Community and self-help (community/patient support groups [32] and health promotion [33]).

Hypotheses testing

After excluding the multiple missing responses for KHOS-I and KHOS-B (n=4), the responses of 82 participants for both subscales against ODIN-Q subscales showed a statistically significant positive linear relationship between the preference for information (KHOS-I) and amount of information received subscale of ODIN-Q ($r = .232$, $p < .05$). This degree of correlation is considered definite but however weak (Guilford, 1950, Rowntree, 1981). Similar but high levels of correlation were found when KHOS subscales and scale compared with each other (Table 3-12).

Table 3-12 The Spearman's correlation coefficients between ODIN-Q and KHOS.

	Amount of information received	Degree of importance	KHOS -I	KHOS-B	Total KHOS score
Amount of information received	1	.102	.232*	-.047	.108
Degree of importance	.102	1	-.114	-.042	-.084
KHOS-I	.232*	-.114	1	.355**	.811**
KHOS-B	-.047	-.084	.355**	1	.816**
Total KHOS score	.108	-.084	.811**	.816**	1

*Correlation is significant at the 0.05 level (2-tailed).
**Correlation is significant at the 0.01 level (2-tailed).

The descriptive analyses of KHOS showed a moderate desire for information (KHOS-I) and high for behavioural involvement (KHOS-B) with the mean scores of 4 (±1.2) and 6.1 (±1.4), respectively (Krantz et al., 1980). The mean total KHOS score was at 10.2 (±2.1) which in turn lies in the lower end of high scores range. Only three (3%) out of 82 participants indicated a low preference for information and two (2%) for behavioural involvement (Figure 3-13).

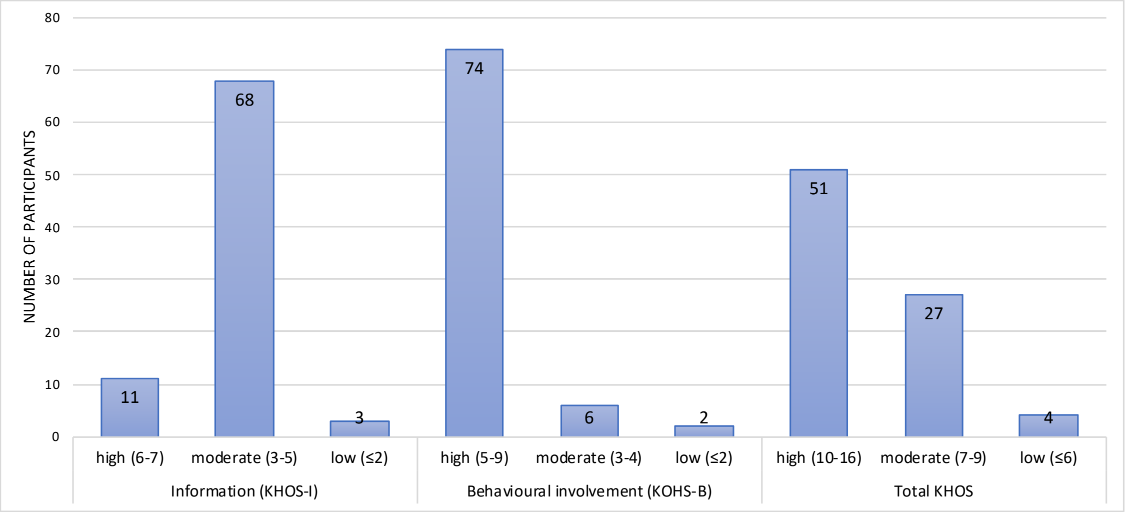


Figure 3-13 The degree of participants' preferences based on the total scores.

The internal consistency (Cronbach's α) was however far under the acceptable cut-off level of 0.70 for both of KHOS-I (-1.20) and KHOS-B (0.19) in addition to the overall scale (0.33). Linear stepwise and ordinal logistic regression (generalised linear models) regression showed that none of the clinical or demographic variables were predictors of the overall KHOS or its subscales scores or toward the preference for information and the overall score, respectively. However, those with a history of cancer have 0.06% less chance to indicate higher preference of behavioural involvement (KHOS-B) (*P* = .031). This effect may however be negligible when considering the limited range of scores for each subscale of KHOS.

Therefore, the final version of doubled-scale ODIN-Q (V 3.0) included 7 demographic questions, 33 items related to the information needs, 2 questions about the preferred sources of information and an open-ended question (Appendix 8).

3.4. Discussion

Information needs of patients with OED

To respond to the patient's IN it is necessary to consider a wider approach that takes in the complexity of the needs for information and its seeking behaviour which is influenced by four main components; why this information is being needed, what factors affecting the information needed (e.g. psychological, behavioural, self-efficacy, demographic, individualistic and environmental factors), the situation and time when information is needed (Wilson, 1997, Wilson, 1999, Ormandy, 2011). It is also imperative to consider that research on health IN especially in cancer care over the past 20 years was incited by health policy initiatives aiming for patient-centred and patient-led health care services (Ormandy, 2011).

Information provision on a chronic and, perhaps, a premalignant disorder such as OED is pivotal as insufficient knowledge can induce the fear of the unknown and uncertainty (Carleton, 2016, Rosser, 2019) and considered as a barrier of dentist-patient discussions and delayed screening of oral cancer (Shepperd et al., 2014, Awojobi et al., 2015). Too much information, in turn, may stimulate anxiety in spite of the patient's desire to disclose the potential complications (Waldron et al., 2011, Brinkmann, 2013) which might be the progression to oral cancer or recurrence of OED lesions in the present example. Individuals might also be distracted when early diagnosis is given, thus, information at this stage is difficult to grasp. Therefore, time consideration is crucial especially with severe disease involvement and short period between diagnosis and treatment (e.g. moderate and severe OED) (Mesters et al., 2001, Chen et al., 2009, Mooney et al., 2013). Therefore, HCPs need to address these elements while using PERMs, such as ODIN-Q to evaluate the sufficiency and priorities of information and design interventions to deliver tailored and timely-oriented information for patients with OED.

Perhaps in parallel with the present study, studies on conditions possibly with a higher link to HPV than OED found insufficient information available to patients about the role of HPV on oral cancer (Lin et al., 2015, Inglehart et al., 2016) and cervical conditions (McCaffery et al., 2005, Rask, 2017b). However, the number of individuals with HPV-associated (koilocystic) OED lesions in the present study (2 out of 86) might not be an accurate reflection to the reality as many of the analysed samples were reported before 1996 when the term was described within the context of OED (Fornatora et al., 1996). Clinicians may consider there to be limited evidence of the role of HPV, or its high-risk subtypes upon the development of OED (Syrjänen et al., 2011, Lerman et al., 2017, Porter et al., 2018).

The high prevalence of reduced psychological wellbeing status noted among patients with OPMDs (Tadakamadla et al., 2017a) and suspected oral cancer diagnosis (Graner et al., 2016) might be one cause for many to perceive psychological support and advice as to the second-highest unmet item in the present cohort. This finding was in line with a study on patients with OPMDs by Lin et al. (2015) who found increased unmet IN among those with higher state anxiety (Lin et al., 2015). Similarly, a systematic review of IN studies related to cancer in Germany found a correlation between increased IN and high scores for anxiety and depression (Pieper, Julich et al., 2015).

Furthermore, the participants in the present study considered the importance of the fear of progression, which can remain persistent despite the reassurance during the consultation and the evidence showing that a few of these lesions will progress to OSCC (Iocca et al., 2019). This fear was also a common outcome after receiving the diagnosis of cancer-linked conditions such as abnormal cells in the cervix (Hellsten et al., 2009, Rask, 2017b). Concerns may remain as toward reporting the risk of malignant transformation of oral precancerous lesions to patients due to the uncertainty toward the calculating personal risk of this transformation (Green, 2013). Instead, providing information about the risk reduction with supplemental sources of information along with verbal communication might be helpful to address this fear while communicating risk information (Garcia-Retamero et al., 2011, Green, 2013).

Despite the difference between the cohort of patients, the present findings of domains with high importance such as treatments, disease and investigative tests were similar to those noted by patients with breast cancer (Galloway et al., 1997) and prostate cancer (Galloway et al., 1997). Similarly, studies of cancer-linked lesions (e.g. abnormal pap smear of the cervix) reported insufficient information receipt on aspects related to the access to information and investigative tests (Rask, 2017b). Furthermore, the individuals in the previous study commonly needed information underlying the desire for behavioural changes such as information about diet and nutrition (Rask, 2017b). This last item was unmet among more than half of the participants in the present study.

In contrast, information about test results and treatments were sufficiently met among the respondents which is similar to studies of oral precancerous lesions (Lin et al., 2015) and oral cancer (Chen et al., 2009). Nevertheless, these previous studies have used non-specific instruments to assess the IN (e.g. using a cancer-generic instrument for precancerous conditions and oral cancer, respectively).

Similar to the findings of Dale et al. (2004), none of the participants indicated having too much overall information despite the concerns from two respondents who were currently smoking and viewed information received about what will happen if one continued smoking/alcohol drinking in excess. Of note, the participants might have understood this choice differently: one participant viewed having too much viewed as a positive action (e.g. information about OED grades, treatment and self-management) and therefore indicating receiving sufficient information. Whereas another participant, who was a current tobacco smoker/alcohol drinker, viewed it as negative such as receiving repeated information about the risk of continuing smoking/alcohol drinking during their clinical visits. Thus, clinicians may consider an individually tailored approach when communicating the advice about smoking cessation and/or alcohol drinking reduction alongside information about the access to professional support (Green, 2013).

The preferred sources to receive information about the disease were also similar to those found by a systematic review of studies investigating IN among patients with cancer with the most common source being health care professionals (mainly medical specialists [e.g. the oncologist]) and the printed information materials as the next (Rutten et al., 2005, Constantinidou et al., 2009). In contrast, all participants in one study considered the Internet as their primary source, some of them felt uncomfortable due to the nature of the information provided or they could not find answers to their concerns (Rask, 2017b) which is likely to be similar as regarding OED (Alsoghier et al., 2018).

Only three variables were significant for correlations with unmet IN; negative correlation with male gender as males were less likely to report unmet IN than females (Galloway et al., 1997, Hsieh et al., 2018) and positive correlation with the increased number of both the current medications (Chen et al., 2009) and medical conditions. The correlations with the latter two variables were found to be negligible. Similar studies found other interactions with other demographic characteristics [e.g. younger age (Galloway et al., 1997, Neumann et al., 2011), lower (Chen et al., 2009) or higher education (Hsieh et al., 2018), ethnicity and who are not working (Hsieh et al., 2018)], tobacco or alcohol status [e.g. the duration of time since quitting smoking or chewing tobacco (Lin et al., 2015), past alcohol drinking (Chen et al., 2009)] or clinical variables [e.g. being symptomatic, having no history of cancer (Lin et al., 2015), number of oral conditions, shorter time since being diagnosed with the disease (Chen et al., 2009) and severe disease (Hsieh et al., 2018)].

Reliability and validity of ODIN-Q

ODIN-Q, which is the first PREM developed specifically to assess IN in patients with OED, has been found to be reliable by achieving excellent internal consistency (Cronbach's α) of 0.91 with an adequate sample size of 86 participants (Mokkink et al., 2019). This is comparable to the two instruments that led to the development of ODIN-Q including TINQ-BC (0.96) and Dale's information needs instrument for prostate cancer (0.91) (Galloway et al., 1997, Dale et al., 2004).

Test-retest reliability measured by weighted kappa's coefficient of the first and second completions showed fair overall agreements for both subscales of ODIN-Q at 0.53 and 0.49 (Cicchetti et al., 1981) with less variation of scores for items (0.20-0.76) compared to the generic needs instruments such as Cancer Needs Questionnaire (0.09-0.94) (Clinton-McHarg et al., 2012) and somewhat similar to the Systemic Lupus Erythematosus Needs Questionnaire (0.32-0.70) (Moses et al., 2005). Comparisons with similar IN instruments are not possible due to different methods to measure agreements including intraclass correlation coefficients (Halkett et al., 2007, Ghisi et al., 2013) or lack of evidence on test-retest reliability (Dale et al., 2004, Alamanou et al., 2016).

ODIN-Q had acceptable validity with its overall content which was initially reviewed and revised by experts who mainly agreed on its relevance and acceptability. Responses on its clarity and redundancy of some items led to a reduction in the number of items to 37, and to 35 items following review by patients. Assessment of structural validity by EFA demonstrated meaningful correlations between items with 91% of these maintained high factors loadings. Only two items were omitted from the revised version of ODIN-Q due to questionable reliability and weak correlations with the extracted factors sought by EFA.

Another aspect of construct validity, hypotheses testing, was found to be adequately addressed as the results showed insufficient information received on all items among patients with a higher number of existing medical conditions than those who have less or none (discriminative validity) (Mokkink et al., 2018b, Mokkink et al., 2019). This was consistent with the hypothesis that proposed that individuals will seek information as a coping strategy when they encounter a stressful event (Lazarus et al., 1984), such as perhaps receiving a diagnosis of “oral precancer” along with other health conditions. However, there was no evidence found that individuals with severe disease (e.g. severe OED) or a history of cancer had higher or lower needs for information.

Despite its limitation, the definite relationship between the amount of information received scale of ODIN-Q and both KHOS subscales confirm its construct (convergent) validity. These findings are potentially explained by the proposed and commonly adopted hypotheses of stress, appraisal and coping theory in health information-seeking behaviour research - that consider the desire for information and behavioural involvement as two of the strategies to maintain the control and coping to a stressful health condition (Lazarus et al., 1984, Rutten et al., 2005, White et al., 2010, Xie et al., 2011). As a result, these participants will have sufficient information and met IN compared with their passive counterparts, as reported with a Spanish cohort that investigated these behaviours using KHOS among 260 patients undergoing oral biopsy (Lopez-Jornet et al., 2012).

Strengths and limitations

Strengths of the present chapter included teaming up patients, clinical staff of all grades, nurses, health researchers and laypersons to develop the first specific instrument that can be useful for clinicians and researchers to identify the needs and priorities for patient information about OED. Moreover, Similar to two studies on the breast (Chalmers et al., 2001) and prostate cancer (Dale et al., 2004), the dual-scale ODIN-Q has the advantages of measuring whether information received on a topic was sufficiently met, and whether this topic is important to the respondent despite their answer in the first scale. Other instruments have only used either of this scales such as degree of importance (Galloway et al., 1997, Feldman-Stewart et al., 2010, Papadakos et al., 2012, Dall'Armi et al., 2013, de Melo Ghisi et al., 2013, Lo et al., 2017) or presented different responses for each item (Hyland et al., 2006).

The ODIN-Q has also undergone a number of steps to evaluate its consistency (reliability) and its inclination to measure what it is intended to measure (validity) whereas some other instruments did not assess these measures while investigating the patient’s IN related to a condition [e.g. ankylosing spondylitis (Cooksey et al., 2012), head and neck cancer (Fang et al., 2012) and gastrointestinal malignancies (Papadakos et al., 2012)] or a clinical service [e.g. rheumatology care (Meesters et al., 2011)].

Although a sample of 86 participants might be considered as adequate for reliability and validity studies of a health measurement (de Vet et al., 2011, Mokkink et al., 2019), it is recommended to have a minimum of five respondents for each variable in the factor analysis (Comrey, 1992) which indicates a minimum sample of 350 respondents for the 35-item ODIN-Q. As the ODIN-Q was developed on a sound theoretical framework that had been used in other information needs questionnaire, the EFA would not be however necessary. Also, the number of recruited participants is reasonable for a single centre study of an uncommon disease with an annual estimated incidence rate at 1-1.5 individuals per 100,000 of the UK population (Nankivell et al., 2012).

Qualitative research remains as the mainstay of recognising the chronic disease impact and its related needs by allowing in-depth assessments and meaningful interpretations (Gerhardt, 1990, Thompson et al., 2011, Padgett, 2012). However, the methods used to develop ODIN-Q, including literature review, previous instruments and experts consensus are commonly adopted for IN instruments (Pian et al., 2019) such as the Derdiarian Information Needs Assessment (Derdiarian, 1986), the informational needs questionnaire for patients with gynaecologic cancer (Papadakos et al., 2012), the Information Needs in Cardiac Rehabilitation tool (de Melo Ghisi et al., 2013), the Head and Neck Information Needs Questionnaire (Dall'Armi et al., 2013) and the Hematological Information Need Questionnaire (Rood et al., 2018). Further research can also consider using the confirmatory factor analysis to test the theoretical framework of ODIN-Q in a large cohort of patients with OED to ensure that its scores represent an adequate reflection of the patient's IN (Mokkink et al., 2010b).

3.5. Conclusion

ODIN-Q showed adequate psychometric properties of reliability and validity specifically to assess IN in patients with OED. Researchers and HCPs are encouraged to use ODIN-Q in a large cohort of patients to achieve the aforementioned objectives and establish more powerful statistical correlations that can highlight individuals who are at higher risk of having unmet needs and design interventions accordingly. The data collected by ODIN-Q could improve the recognition of IN patterns changes from the diagnosis to the treatment that collectively enhances the need-driven informational provision and tapering the focus of HCPs in the care of OED.

CHAPTER IV. INFORMATION NEEDS CONCERNING ORAL EPITHELIAL DYSPLASIA – CAN CLINICIANS PREDICT THE INFORMATION NEEDED BY PATIENTS?

4.1. Background

The use of the term ‘concordance’ has often now replaces other terms used in a similar context such as ‘compliance’, ‘adherence; and ‘cooperation’ (Mullen, 1997, Segal, 2007). The latter terms were criticised as they may not focus upon the patient’s wish when it comes to their health-related decision-making, but possibly a concession to the expectations of the health care professionals (HCPs) (Mullen, 1997, Horne et al., 2005). Concordance, in turn, recognises tailored and consensual therapeutic plans with a sufficient exchange of information and discussions to make informed decisions on what is best for the patients themselves, meeting their expectation and therefore leading to higher satisfaction and health outcomes (Mullen, 1997, Rao et al., 2000, Wittmann et al., 2011). However, the resistance remains as of today to employ this term in clinical practice with its political and economic imperatives despite its early introduction in the 1970s (Segal, 2007, Cribb, 2011). In clinical care of chronic disease, the patient-HCPs concordance is illustrated by establishing a patient-HCPs partnership with tailored information provision and patient-centred communication that collectively contribute to informed decision-making (Figure 4-1) (Jordan et al., 2002, Cribb, 2011, Sidorkiewicz et al., 2019).

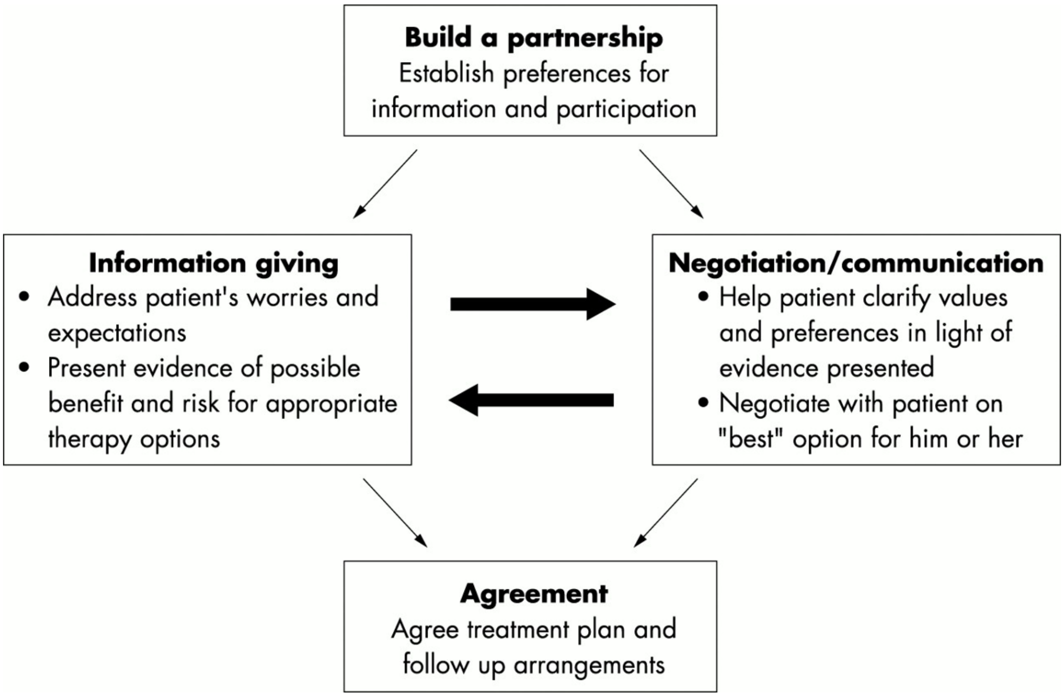


Figure 4-1 The concordance cycle: from establishing a partnership to making informed decisions (Jordan et al., 2002).

Studies have investigated the role of patient-HCPs agreements toward supportive needs and decision-making (Perrin et al., 2000, Söllner et al., 2001, Shin et al., 2013), disease impact and activity (Hudson et al., 2010, Smolen et al., 2016, Crespo-Lessmann et al., 2017), treatment (Heisler et al., 2003, Okubo et al., 2018, Bolt et al., 2019) and assessments of general (Geest et al., 2004) and oral health (Atchison et al., 1993). Other studies investigated this agreement with broader health care practice such as clinical care and outcomes (Greene et al., 1989, Maly et al., 2002, McDonald et al., 2011, Gross et al., 2013, Calpin et al., 2017) and the essence of patient-HCPs concordance in patient education (Potts et al., 1984, Waitzkin, 1984, Silvers et al., 1985).

Some studies investigated this concordance concerning information related to chronic conditions such as cancer and found a notable disagreement; '*where the* *family go if they need help, 'emotional reactions that are normal during a crisis'* and *'I will need help to take care of myself when I come home'* related to oesophageal cancer (Andreassen et al., 2007a); *'if the prostate cancer is not treated'* and *'how long will I live'* (Ruesch et al., 2014) and prognostic information about chemotherapy for colorectal cancer (Elkin et al., 2007). Due to the importance of such concordance, instruments were specifically developed and validated for this purpose such as the 10-item Patient-Physician Discordance Scale which aimed at assessing the concordance toward health status and clinical visit (Sewitch et al., 2003).

These studies encouraged clinicians to address the patient's preferences for information at different phases of clinical care. There is a current lack of studies that objectively measure patient-clinician concordance toward information needed on premalignant and cancer-linked conditions and indeed oral epithelial dysplasia (OED). A commonly implemented objective method to assess this concordance is through self-administered questionnaires (Ancel, 2012, Ruesch et al., 2014). By using ODIN-Q, this chapter aimed to assess whether clinicians, with different grades and specialities allied to dentistry, are able to predict the highly important information domains and topics to patients concerning OED. The secondary aim was to assess the degree the patient-clinician, patient-patient and clinician-clinician agreements on these domains and topics. Thus, the questions addressed by the present chapter included (1) do clinicians agree with patients on the important items and (2) to which degree clinicians agree with each other compared to patients.

4.2. Methods

This was a prospective and cross-sectional study to assess the concordance between the responses of eighty-six patients, who completed ODIN-Q (Chapter 3 and Appendix 7) to those of clinicians.

4.2.1. Study eligibility criteria

Clinicians who routinely manage patients of chapter 3 in clinical care settings allied to dentistry (e.g. general dental practice, oral medicine, oral surgery and oral and maxillofacial surgery).

4.2.2. Study measures

In addition to the invitation letter (Appendix 9), the study questionnaires (Appendix 10) included:

1. Demographic and professional background: Information about age, gender, and the number of years in practice after obtaining the postgraduate qualification were obtained to determine the predictors of patient-professional agreement.
2. The 33-item clinician's version of ODIN-Q, which only included the degree of importance scale (McNair et al., 2013).

As the clinicians' version of ODIN-Q was developed before the pilot testing of ODIN-Q by patients, slight differences existed between the initial and later versions on the wording of two items; (1) '*The odds of treatment success (cure/recovery rate)'* versus *'chances of a cure'* and (2) '*About the diet and nutrition (e.g. ways of* *managing the disease/treatment symptoms'* versus *'information about diet and nutrition',* respectively. Therefore, these items were excluded from the present analyses.

4.2.3. Clinicians' recruitment

The questionnaires were disseminated using different approaches to include a broader population of clinicians who routinely look after patients with OED, including:

- Web-based clinician's version
    - An introductory email was sent to the administrators of the national and international professional bodies allied to oral medicine namely London Oral Medicine Group, British Society for Oral Medicine [BSOM] and European Association of Oral Medicine [EAOM]). Permissions were obtained to disseminate the survey to the members of these bodies.
    - The email included the background of the study and a link to the study questionnaires using a premium online survey software (https://www.surveymonkey.com).

- Printed clinician's version
    - The organisers of the EAOM's 14th Biennial Congress commenced in September 2018 in Gothenburg; Sweden gave their prior permission to distribute the printed version during the congress.

  - The delegates were approached during the congress and invited to participate in the study.
  - Those who agreed to participate were given the questionnaire to complete during the 3-day congress and return the completed ones by hands or to the congress registration.

4.2.4. Data analysis and representation

Unlike the other studies of concordance between patients and their clinicians (Söllner et al., 2001, Shin et al., 2011, Ruesch et al., 2014), the invited clinicians were not involved in the care of the recruited patients with OED for proportionate comparisons. Therefore, methods from similar studies were followed:

- *Demographic and professional data:* each of demographic and professional variables of clinicians (e.g. gender, postgraduate degree, speciality, number of patients seen regularly, years of practice and country of practice) were presented in numbers and percentages (Rao et al., 2000).
- *Scores description and comparisons*: the mean and median of each item and domain across the degree of importance scale for of ODIN-Q were calculated and compared between both groups (Shin et al., 2011).
- *Concordance between clinicians and patients*: both of responses to the degree of importance scale of ODIN-Q were compared as agreement by per cent (important or not important) and weighted kappa (*k*) coefficients for ordinal data (very important=4, important=3, not very important=2 and not important at all=1) (Dale et al., 2004, Elkin et al., 2007, McNair et al., 2013). Values were interpreted as fair or poor based on a cut-off value of 0.40 (Cicchetti et al., 1981).

- *Inter-rater agreement:* The agreements among the examined groups were assessed using Fleiss kappa test (Fleiss, 1971), which has been used to assess the agreements between more than two raters on IN concerning prostate cancer (Ruesch et al., 2014). Fleiss's interpreted these values as poor (≤0.40), fair to good (0.41-0.75) and excellent (>0.75) (Fleiss et al., 2013).
- *Missing data*: similar to the validation study, questionnaires with ≤10% nonresponse items were matched to the average answer (individual mean imputation) (Shrive et al., 2006, Eekhout et al., 2014). Responses with more than 10% missing data were excluded to avoid skewed estimates.
- Multivariable regression analyses aimed to predict the factors associated with significant scores. The statistical significance level is considered with $p = 0.05$ (two-tailed test) (Heisler et al., 2003, Elkin et al., 2007).

The clinicians' and patients' responses to ODIN-Q were presented in a Microsoft Excel (version 16.32) proforma with numerical representation as very important=4, important=3, not very important=2 and not at all important=1. IBM SPSS statistical software (version 22.0) was used to assess the concordance and significant correlations. Items which patients responded with 'not applicable' choice were excluded from the analyses to avoid the skewness of data (Boberg et al., 2003).

4.2.5. Ethical consideration

While ethics was obtained for the patients' study, as noted in chapter 3, no ethics needed for the clinicians. Both if the printed and online versions of the survey were anonymous and in line with the Data Protection Act 2018 (Health Research Authority, 2018). The administrators of London Oral Medicine Group, BSOM and

EAOM have kindly agreed to distribute the invitation email and link to the survey (e-version) to their members. The EAOM's team provided their written confirmation to distribute the printed version during their bi-annual congress in 2018.

4.3. Results

4.3.1. The demographic and educational background of the clinicians

Eighty-seven participants completed the study questionnaires. Individuals who described themselves as non-clinicians were excluded. After the initial assessment, further exclusion to seven electronic and two printed questionnaires due to multiple missing responses (>4 missing responses). Therefore, the analyses included 77 participants for the electronic (n=44) and printed (n=34) surveys. The response rate could not be determined for both of the electronic and printed versions as the survey was distributed anonymously.

The characteristics of the recruited clinicians are shown in table 4-1. Males represented 53% of those clinicians. As some participants had more than a speciality affiliation, all clinicians had oral medicine and oral surgery affiliations along with dental-allied specialities including general dentistry (n=5), oral pathology (n=2), restorative (n=1), special care (n=1), facial pain (n=1), radiology (n=1) epidemiology (n=1). With one or more postgraduate qualification, the most common was the speciality training (42%) followed by a PhD (38%) and Master's (16%) degrees. Half of the participants (48%) indicated routinely seeing ten or less OED patients in an average month. Regarding the number of years in the practice, 57% and 20% of clinicians had ten or fewer years and more than 15 years' in their speciality practice, respectively.

Table 4-1 The demographic and professional backgrounds of the clinicians (n=77)

Variable	Category	Number of participants (%)
Gender	Male	41 (53%)
	Female	35 (45%)
	Preferred not to say	1 (1%)
Speciality (one or more choice)	Oral medicine	66 (85%)
	Oral surgery	12 (15%)
	Oral pathology	2 (3%)
	Others	10 (13%)
	General dentistry	*5*
	Special care dentistry	*1*
	Facial pain	*1*
	Other dental speciality (radiology, epidemiology and restorative dentistry)	*3*
Qualification (one or more choice)	Higher diploma	7 (9%)
	Speciality training	32 (42%)
	MSc/MS	12 (16%)
	PhD	29 (38%)
	Others *(MD, speciality training and no postgraduate degree*)	4 (5%)
Average number of OED patients in an average month	Less than 5 patients	12 (16%)
	5 to 10 patients	25 (32%)
	Between 10-20 patients	9 (12%)
	More than 20 patients	14 (18%)
Number of years in practice	Less than 5 years	24 (31%)
	5 to10 years	20 (26%)
	10-15 years	16 (21%)
	More than 15 years	16 (21%)

The participants were practicing in 24 different countries located in 5 continents (Europe, North and South Americas, Asia and Australia) with the majority in the United Kingdom (n=22), Sweden (n=12) and Italy (n=10). Other countries were Romania (n=4), USA (n=4), Greece (n=3), Australia (n=2), Cech Republic (n=2), Saudi Arabia (n=2), Brazil (n=1), Croatia (n=1), Finland (n=1), Indonesia (n=1), Ireland (n=1), Israel (n=1), Jordan (n=1), Lebanon (n=1), Malaysia (n=1), Netherland (n=1), Qatar (n=1), Russia (n=1), Spain (n=1) and Poland (n=1),

4.3.2. Do clinicians agree with patients on the important items?

In contrast to the 86 patients who viewed 31 out of the 33 ODIN-Q items as important, clinicians have only considered 25 items as important with median scores of 3 or above on the 4-point importance scale. However, the clinicians' overall average rating of 3.17 (highest = 3.76, lowest = 2.28) was similar to patients' average score of 3.23 (highest = 3.68, lowest = 2.19). They were also able to predict 7 out of the nine top scored items by patients - based on their median scores (Table 4-2).

Table 4-2 The highest scored ODIN-Q items by patients and clinicians.

Patients			**Clinicians**		
Item	*Domain*	*Score*	*Item*	*Domain*	*Score*
The fear of progression to cancer*	Psychosocial aspects	3.71	Disease grades and risk of developing mouth cancer*	Disease information	3.79
Disease grades and risk of developing mouth cancer*	Disease information	3.71	The fear of progression to cancer*	Psychosocial aspects	3.78
Screening and early detection*	Investigative tests	3.67	What OED is?*	Disease information	3.75
What will happen if it is not treated?*	Treatment	3.64	What will happen if continues to smoke or drink alcohol?	Disease information	3.74
Treatment options and how each treatment works?*	Treatment	3.61	What will happen if it is not treated*	Treatment	3.72
What OED is?*	Disease information	3.59	Risk factors for developing OED	Disease information	3.70
What is likely to happen to OED in the future?*	Disease information	3.58	Treatment options and how each treatment works?*	Treatment	3.67
How frequent and severity are the symptoms?	Physical aspects	3.58	What is likely to happen to OED in the future?*	Disease information	3.67
Coping with the possible effects of the disease/ treatment?	Psychosocial aspects	3.55	Screening and early detection*	Investigative tests	3.61

**The item is considered highly important by both of patients and clinicians.*

Notably, patients provided higher scores to items on investigative tests, physical and psychosocial aspects domain and slightly similar scores on information about the disease, treatments and medical system and access to information domains to those indicated by clinicians (Figure 4-2).

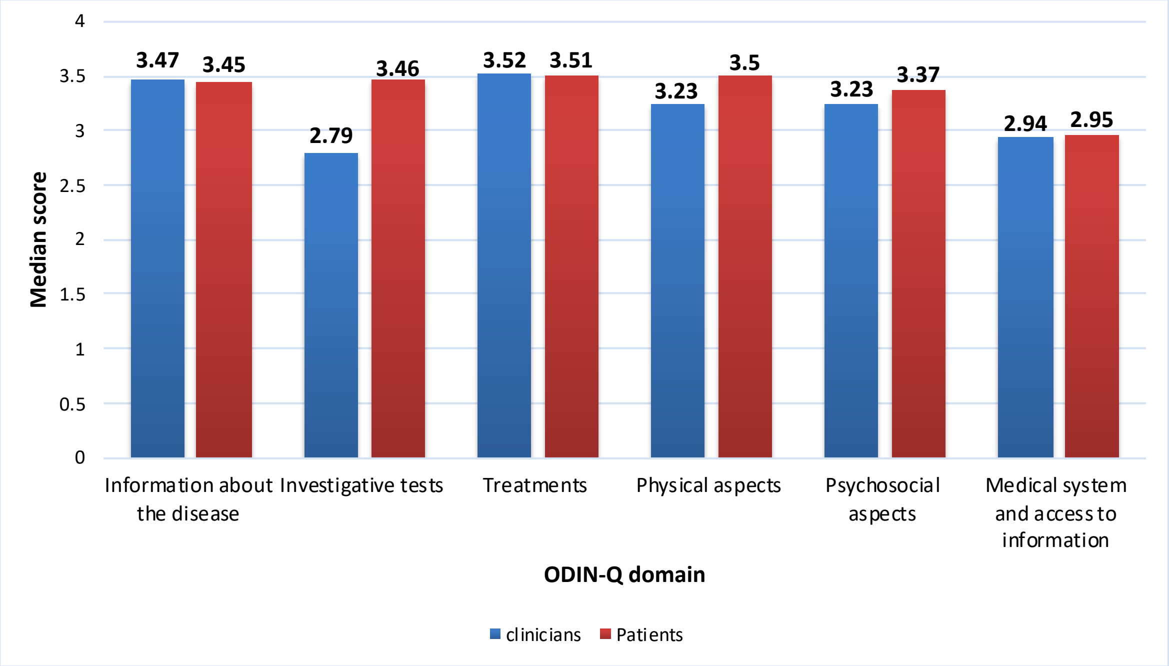


Figure 4-2 Ratings of each domain of ODIN-Q by clinicians and patients.

Moreover, patients provided higher scores to 13 items they considered necessary including *how frequent and severe are the symptoms* (3.58 versus 3.27), *coping with the possible effects of the disease/treatment* (3.55 versus 3.35), *self-management at home* (3.5 versus 3.28), *how the disease/treatment affects daily physical activities* (3.50 versus 3.23), *how it looks in the mouth or lips* (3.48 versus 3.28), *the experience of the doctor and other health care staff* (3.46 versus 3.15), *benefits, risks, how each test works, and the meaning of test results* (3.46 versus 2.79), *chances of spreading to an adjacent or distant body part* (3.42 versus 3.03), *how common is it* (3.22 versus 3), *whether it is contagious or not* (3.44 versus 3.05), *the genetic testing and chance of inheritance to children* (3.11 versus 2.26), *the role of HPV* (3.03 versus 2.66) and *research and recruitment for clinical trials* (3 versus 2.58). A similar response was also noted on an item of less importance to patients about *complementary and alternative medicine* (2.64 versus 2.25) (Table 4-3).

In contrast, the patients had lower scores than clinicians on items such as *risk factors for developing OED* (3.47 versus 3.72), *what will happen if continues to smoke or drink alcohol* (3.39 versus 3.74 and *the lifestyle adjustmen*t (3.2 versus 3.59).

Some agreements were however noted on important items (median = ≥3) such as '*disease grades and risk of developing mouth cancer', 'fear of progression to cancer, screening and early detection', 'what will happen if it is not treated', 'treatment options, benefits, risks, and how each treatment works', 'what OED is', 'what is likely to happen to OED in the future', 'physical support and advice', 'how the disease/treatment affects the quality of life', 'how the disease/treatment affects social life'* and '*what is a safe level of alcohol to drink'*.

Table 4.3 shows the weighted *k* values of concordance between clinicians and patients with an overall average poor agreement of 0.06. The highest level of agreement was with '*seeking another professional opinio*n' and *how it looks in the mouth or lips* (0.24) followed by the screening and early detection (0.13) and '*benefits, risks, how each test works, and the meaning of test results'* (0.14), respectively. In contrast, a notable discordance was seen on *the health promotion*

(-0.099), '*fear of progression to cancer*' (-.091) and '*coping with the possible effects of the disease/treatment*' (-0.074), respectively. Comparable findings were found at the domain level with all average values below 0.1: investigative tests (0.076), disease information (0.028), treatments (0.002), physical aspects (0.007), access to medical information (-0.014) and psychosocial aspects (-0.057).

A separate analysis was conducted, to see whether UK clinicians would have higher agreement on all items with patients, showed slightly similar average overall value (0.053) with fair agreements on the role of HPV (0.465) compared with all participant clinicians. The least agreements were noted on '*what OED is*' (-.25), '*how common is it*' (-.22), '*about treatment options, benefits, risks, and how each treatment works*' (-.21*), 'what is a safe level of alcohol to drink'* (-.18) and *'how frequent and severe are the symptoms'* (-.17).

Table 4-3 Patients' and clinicians' ratings and concordance on ODIN-Q items (n=33).

Domain	**ODIN-Q item**	**Median (mean) importance score**		**Concordance***	**Percentage of patients/ clinicians (%)**	
		Patients	Clinicians	Weighted *k* coefficient	Important	Not important
Information about the disease	What OED is?	3.59 (3.55)	3.75 (3.7)	.050	95/95	5/5
	How common is it?	3.22 (3.12)	3 (2.98)	.056	84/74	16/26
	Risk factors for developing OED.	3.47 (3.38)	3.72 (3.7)	.049	87/97	13/3
	How it looks in the mouth or lips?	3.48 (3.43)	3.28 (3.24)	.244	93/13	7/87
	Whether it is contagious or not?	3.44 (3.39)	3.05 (2.98)	.095	94/74	6/26
	The role of HPV.	3.03 (2.91)	2.66 (2.67)	.028	74 /58	26/42
	Disease grades and risk of developing mouth cancer.	3,71 (3.65)	3.78 (3.76)	-.144	96/97	3/3
	What will happen if continues to smoke or drink alcohol?	3.39 (3.26)	3.74 (3.71)	-0.006	84/95	16/5
	What is a safe level of alcohol to drink?	3.14 (3.02)	3 (2.97)	-0.015	76/74	24/26
	What is likely to happen to OED in the future?	3.58 (3.53)	3.67 (3.73)	-.069	94/95	6/5
Investigative tests	The screening and early detection.	3.67 (3.62)	3.61 (3.57)	.138	94/95	6/5
	The genetic testing and chance of inheritance to children.	3.11 (2.90)	2.26 (2.98)	-.022	72/36	28/64
	Benefits, risks, how each test works, and the meaning of test results.	3.46 (3.40)	2.79 (2.81)	.114	89/63	10/37
Treatments	What will happen if it is not treated?	3.63 (3.60)	3.72 (3.71)	-0.06	95/99	5/1
	Treatment options, benefits, risks, and how each treatment works.	3.61 (3.58)	3.67 (3.66)	.056	94/99	6/1
	How the disease/treatment affects the quality of life.	3.51 (3.45)	3.52 (3.49)	-0.007	91/94	9/6
Physical aspects	Self-management at home.	3.5 (3.45)	3.28 (3.22)	0.079	93/77	7/23
	Complementary and alternative medicine.	2.64 (2.60)	2.25 (2.28)	-0.054	58/32	49/68

	How frequent and severe are the symptoms?	3.58 (3.50)	3.27 (3.23)	-.055	95/86	5/14
Physical aspects	Chances of spreading to an adjacent or distant body part.	3.42 (3.33)	3.03 (2.93)	.050	89/76	10/24
	How the disease/treatment affects daily physical activities.	3.50 (3.43)	3.23 (3.18)	.026	92/87	8/13
	Fear of progression to cancer.	3.71 (3.29)	3.78 (3.75)	-.040	98/96	2/4
chosocial spects	Coping with the possible effects of the disease/treatment.	3.55 (3.50)	3.35 (3.33)	-.091	93/95	7/5
	How the disease/treatment affects social life.	3.20 (3.10)	3.12 (3.07)	-.074	78/74	22/26
	How the disease/treatment affects job/career.	2.75 (2.70)	2.9 (2.92)	-.023	63/70	37/29
Medical system and access to information	The experience of the doctor and other health care staff.	3.46 (3.40)	3.15 (3.12)	-.024	93/83	7/17
	Seeking another professional opinion.	2.83 (2.75)	2.73 (2.74)	.002	63/68	37/31
	Physical support and advice.	3.51 (3.44)	3.44 (3.4)	-.013	91/91	9/9
	Psychological support and advice.	2.89 (2.82)	2.90 (2.87)	.033	64/73	35/27
	Community/patient support groups.	2.06 (2.18)	2.56 (2.57)	-.033	35/53	65/47
	Health promotion (e.g. promoting one's health literacy).	2.75 (2.70)	3 (2.94)	-.099	63/73	37/27
	The lifestyle adjustment	3.2 (3.04)	3.59 (3.54)	-.026	78/91	22/9
	Research and recruitment for clinical trials.	3 (2.91)	2.58 (2.59)	.045	71/51	29/9

**Concordance refers to the patient-clinician agreement based on the 4-tier importance scale (very important, important, not important and not at all important).*

Analysis of the responses based on the binary scale (important and not important) indicated that both groups had very high agreement percentages on the importance of *what OED is* (100%), *physical support and advice* (100%), *disease grades and risk of developing mouth cancer* (99%), *what is likely to happen to OED in the future?* (99%), *the screening and early detection* (99%), *fear of progression to cancer* (98%) and *coping with the possible effects of the disease/treatment* (98%).

In contrast, clinicians tended to underestimate the importance of '*how it looks in the mouth or lips?*' with 13% of them noted its importance compared with 93% of patients. Similarly, a discordance was also noticed on *the genetic testing and chance of inheritance* (32% versus 72%), *complementary and alternative medicine* (32% versus 58%) and *how each test works and the meaning of test results* (63% versus 89%).

4.3.3. Degree of agreement between clinicians

Fleiss Kappa's coefficients showed very poor inter-rater agreements on the item level with an overall value at 0.090 [95% CI: 0.084-0.097 (P<.05)]. The analyses of domains showed similar results with the highest value on psychosocial and physical aspects (0.272 and 0.193, respectively) and the lowest on investigative tests (-0.014).

Despite the low agreements, clinicians practising in the UK showed a slightly higher overall k value at 0.105 [95% CI: 0.099-0.112 (P <0.05)] amongst themselves. Nevertheless, patients presented slightly higher agreements with each other shown by a value of 0.251 [95% CI: 0.242-0.261 P <0.05] at the item level and fair to a good agreement on physical aspects domain (0.50).

What were the predictors of providing high or low importance scores by clinicians?

There were no statistically significant correlations shown by multinomial logistic regression with the total sum scores [dependent variable] and each of clinicians' characteristics such as gender, postgraduate degree (higher diploma, speciality training, MSc/MS, PhD and a combination), speciality (oral medicine, oral surgery, others and a combination), the number of patients regularly seen every month (<5 patients, 5-10, 11-20 and >20) and years in practice as specialist (<5 patients, 5-10, 11-16 and >15) [independent variables].

4.3.4. Comments from clinicians

Eight clinicians provided written feedback:

i. The overall content of ODIN-Q; ***'In my opinion it is not absolutely important to give too many information to the patient. It's enough for him [the patient] to know only basic, clear information and the periodic control'*** (study ID, 02), ***'Most seems important'*** (03), ***'Interesting range of questions'*** (08) and ***'All of the above would be of interest to a patient diagnosed with OED'*** (14).
ii. Specific items of ODIN-Q; '***Q9*** **[What is a safe level of alcohol to drink?].** ***Government guidance on weekly alcohol consumption relates to general health and not specifically development of oral cancer/PMLs'*** (10).
iii. Disagreement with the term OED and the need to add additional questions; ***'Please forgive me but i do not agree with the term OED. OED is not a clinical term and not easily understandable among patients I would prefer to use for my patient "Oral lesions with risk of malignancy". Please provide extra questions about the location, size and morphology of OED,***

aetilogic [aetiologic] factors, younger age of exposure and their importance to your patients.' (20).

iv. Disagreement with the cover letter of the questionnaire (Appendix 12); ***'I would disagree with the premise that www resources are poor; the purpose of the work seems redundant.'*** (41).

v. Importance of raising the awareness of dental practitioners and empowering the research; ***'I believe that raising awareness among general dental practitioner to refer the patient with OED to a hospital setup and mark the referral urgent. Investing in research and RCT is crucial.'*** (23).

4.3. Discussion

This is the first study to investigate the concordance between clinicians and patients regarding the importance of information concerning OED. The principal study findings showed that clinicians, currently practicing in 24 countries and seeing 5-10 patients with OED on an average month, were able to predict seven of the nine highest scored aspects of information. Nevertheless, they poorly estimated the degree of importance based on the 4-responses scale for all items with *k* coefficient at 0.06. Similar findings were reported regarding the supportive cancer care needs in Korea by Shin et al. (2011), who noted weak patient-clinician agreements on supportive care needs with *k* coefficients between 0.04 and 0.15. Likewise, they noted a poor overall agreement of 0.16 on cancer-related information (Shin et al., 2011). Elkin et al. (2007) showed a further low degree of agreement on cancer-information preferences of elderly patients and their physicians of -0.11.

If it is not unexpected that there will be some discordance between what information patients wish and what clinicians can provide – or think relevant. The discordance (at least with UK patients) was with clinicians across the globe, but when the responses of UK clinicians on how important were the ODIN-Q items compared to those of patients, a significant agreement was found on the role of HPV in OED, which remain controversial and not well-studied (Speight, 2007, Angiero et al., 2010, Lerman et al., 2017, Gomez-Armayones et al., 2019). Whereas topics with notable discordance between UK clinicians and patients included, aside from these related to the OED and its symptoms, what is a safe level of alcohol to drink. Notably, there is a lack of specific and evidence-based guidelines toward the lifestyle factors related to the cause and malignant potential of OED such as alcohol consumption. The available guidance on the safe/recommended level of alcohol consumption per week is related to the general health rather than oral health (UK Department of Health, 2016) as noted by one of the clinicians (study ID, 10) or cancer prevention in general (Kushi et al., 2012). Interestingly, 88% of the patients in the present study had at least one of OPMDs, and more than half of them noted the importance of dietary advice and noted unmet needs towards it [chapter 3].

In line with the findings of this study, Ruesch et al. (2013) noted that regarding prostate cancer both of HCPs and patients agreed on the importance of what the disease is and what will happen if it is not treated. Furthermore, the research of other studies of other diseases echoed the present results as patients perceived higher needs than clinicians for information about self-management at home, the treating clinicians and symptoms (Shin et al., 2011) but expressed lower needs to lifestyle adjustment (Suhonen et al., 2005) than HCPs. Furthermore, HCPs generally underestimated the

IN for both of the patients with oesophageal cancer and their families (Andreassen et al., 2007b). The previous study also found that physicians presented lower average score to psychosocial aspects subscale compared to those by patients which is similar to what was found in the present study.

With both of patients and clinicians presently designating the importance what will happen if no treatment is being provided for OED, there is no robust evidence that support the surgical management over watchful waiting to reduce the rate of malignant transformation of OED lesions due to the lack of well-designed studies (Lodi et al., 2006, Nankivell et al., 2012, Field et al., 2015, Tilakaratne et al., 2019). This may raise concerns about the ’overtreatment’ for surgical removal of precancerous lesions compared to watchful waiting approach with questions remain on whether these procedures would reduce morbidity, malignant transformation, psychological harm and cost-effective (Esserman et al., 2014, Strander et al., 2014, Nghiem et al., 2016).

Although one of the clinicians noted that the web resources related to OED are sufficient (study ID, 41), the contrary was found by a recent study (Alsoghier et al., 2018) that examined 900 websites in the English language and found a lack of content specifically related to OED with the quality, readability and actionability of available content being poor. This may leave individuals with OED with insufficient and inappropriate information that could induce anxiety and fear which act as a deterrent of reporting oral cancer symptoms to the dentist (Eijkman, 2007, Baumgartner et al., 2011, Waldron et al., 2011, Brown et al., 2018). Supporting individuals who had a high risk of oral cancer with an information leaflet and informative discussions about the early presentation of oral cancer led to better symptoms appraisal, higher ability to perform mouth self-examination and higher confidence to seek professional help for worrying symptoms than those who had no intervention (Lee et al., 2019).

Challenges arise upon ensuring exchange of information during the sometimes limited time frame for a clinical visit (Freeman et al., 2002, Mira et al., 2010). For this reason, maintaining the patient-clinician concordance on information concerning OED is essential to maintain primary prevention of oral cancer by reducing the disease risk factors (Thomson, 2015, Awadallah et al., 2018). Examples of this prevention can include smoking cessation, reducing alcohol consumption and modifying the dietary pattern which has been recommended for OPMDs [e.g. oral leukoplakia, oral lichen planus and oral submucous fibrosis] as to reduce the molecular events leading to carcinogenesis of the mouth (Touger-Decker et al., 2014, Thomson, 2015, Panta et al., 2018). These behavioural changes are however commonly being determined by the individual’s self-efficacy and believe in their self-control and require sufficient information about the disease (OED) to be maintained (Leventhal, 1971, Bandura, 1977, Wallston et al., 1978, Bandura, 1994, Bellamy, 2004).

The findings from the present study and previous studies of medical literature encourage clinicians to assess the patient’s needs and preferences for information concerning OED and consequently the understanding of the presented information to maintain an effective patient-clinician communication and information exchange. These needs and preferences can be assessed using instruments such as ODIN-Q and Krantz Health Opinion Survey (Krantz et al., 1980). Whereas the understanding and knowledge can be assessed by simply asking *“tell me what you know about your diagnosis”* and whether the patient knows specific information about their diagnosis that might not be easy to comprehend (Bultz et al., 2011), such as “dysplasia”, “biopsy”, “risk of mouth cancer” or their clinical and/or histopathological diagnosis with OPMDs such as “oral lichen planus”. The main topics for discussion need to be previewed first, summarised and then linked to next agreed actions to improve understanding and retention (Bultz et al., 2011). If these steps help to address the patient’s concerns and obtain their satisfaction in less number of visits, it can result in a better health care utilisation and correspondingly reduced expenditure (Schumacher et al., 2013).

Strengths and limitations of the study

The present study used a specific and initially validated (content validity) questionnaire to assess IN concerning OED. In addition, the sample size of 86 patients and 77 clinicians are considerably high for a disorder with low incidence rate as well as this of questionnaire-based concordance studies on IN between oesophageal cancer patients (n=15) and HCPs (n=34) (Andreassen et al., 2007b) as well as the desire for information among elderly cancer patients (n=73) and oncologists (n=19) (Elkin et al., 2007).

The study is presented with some limitations, such as assessing the concordance between patients and not-treating clinicians. Therefore, it was not possible to assess the predictors for high or low concordance related to patients [e.g. demographics including the age, gender and socioeconomic status (Shin et al., 2011, Ancel, 2012)] or their disease [e.g. time since being diagnosed (Ancel, 2012) and severity (Perrin et al., 2000)] and clinicians [e.g. length of experience (Shin et al., 2011)]. Moreover, the present study did not assess patient satisfaction or trust in clinicians and its relevance to the concordance with their clinicians (Shin et al., 2011).

The low sample size was another limitation of the present study was however seen with another single-centre feasibility study for chemoprevention of OED which has stopped after 15 months due to unsatisfactory recruitment rate (Nankivell et al., 2012). The authors attributed this low rate to the low incidence of OED in the UK (~1.5/100,000 per annum). A similar issue was encountered in the present study, with only 86 patients recruited over 15 months in two of the busiest oral medicine and oral and maxillofacial clinics in the UK.

Furthermore, a high number of ineligible patients was noticed; 63% of identified records being initially excluded due to inactivity, inaccessible records and recent diagnoses of malignancies in the mouth and elsewhere. Thus, information about research and clinical trials might be presented during discussions with patients – when available. Interestingly, 71% of the patients viewed information about research as important compared to half of the clinicians. The governmental and non-profit funding bodies may also consider higher contribution to fund this type of research and clinical trials as noted by one of the clinician respondents (study ID 23).

4.4. Conclusion

The present study has found that clinicians were generally able to predict the important topics of the information needs of patients with OED but did not predicts how important patients considered each of these. Clinicians underestimated the importance ratings of thirteen items and overestimated three items compared to patients. All clinicians and patients agreed on the importance of what OED is and the physical support and advice, however, only 13% of clinicians thought of how OED looks in the mouth or lips as important compared to 93% of patients. Also, clinicians had less agreement amongst themselves compared to the patients. The present findings should encourage clinicians to assess the patient’s IN, possibly with instruments such as ODIN-Q, for tailored and patient-centred communication during consultations. Also, qualitative studies are necessary to present a detailed description and interpretation of the information exchange during consultations to support the patient-centredness in clinical care communications.

CHAPTER V. DENTAL ANXIETY, ANXIETY AND DEPRESSION AND QUALITY OF LIFE IN PATIENTS WITH ORAL EPITHELIAL DYSPLASIA

5.1. Background

Assessing anxiety and depression symptoms is essential in clinical care and education of patients diagnosed with a chronic and cancer-linked disorder such as, perhaps, oral epithelial dysplasia (OED). Anxiety is defined as *'apprehensive anticipation of future danger or misfortune accompanied by a feeling of dysphoria or somatic symptoms of tension'* (American Psychiatric Association, 1994). Whereas depression covers '*a wide range of states, from feeling sad, helpless, or demoralized to grief, poor self-esteem or a major depressive episode'* (McDowell, 2006). The prevalence of symptoms related to these two clinical diagnoses is not uncommon in studies that included patients with conditions that may increase the risk of cancer or trigger cancer worry. For instance, a higher prevalence or grade of anxiety and depression symptoms was found in patients with intraepithelial neoplasia of the vulva (Shylasree et al., 2008, McFadden et al., 2009) compared to the general population (Crawford et al., 2001). Similarly, the prevalence of these symptoms among those with oral lichen planus was higher than the control group from the same study population (Vilar-Villanueva et al., 2019) or in comparison with the general population of other studies (McCartan, 1995, Wiriyakijja et al., 2020).

To assess anxiety and depression, the previous studies used the self-completed Hospital Anxiety and Depression Scale (HADS), which has been highly used to distinguish and identify those who their scores of clinical significant of both symptoms in different languages, forms (printed- and computer-based), and populations (patient and general population) (McDowell, 2006, Djukanovic et al., 2017). HADS subscales for anxiety (HADS-A) and depression (HADS-D) have shown high internal consistency scores (Cronbach's α) in a general population [0.80 and 0.76] (Mykletun et al., 2001) as well as in cohorts of patients with cancer [0.93 and 0.90] (Moorey et al., 1991), oral lichen planus [0.87 and 0.84] (Wiriyakijja et al., 2020) and stomatological diseases [0.83 and 0.82] (Llewellyn et al., 2003).

The Dental anxiety (DA), which affects 3-10% of a population, is another possible impediment of seeking professional help “dental avoidance” when encountering worrisome symptoms and it affects the individual's ability to absorb and recall the given information (Kőszegi, 2003, Chen et al., 2009, Armfield et al., 2015, Brockbank et al., 2015). DA is as '*a state of anxiety'* related to the dental care that can be anticipated among individuals who are frequently missing, cancelling or arriving late for their visits and/or missing their periodic follow-up appointments (Weiner, 2011). The dental avoidance, which can take up to 20 years, is a common result of DA (Eitner et al., 2006) and its levels are likely to be in concordance with the levels of dental anxiety (Hakeberg et al., 2013). Dental fear can also impede the motivation to perform self-examination, which is known to reduce oral cancer-related mortality and morbidity among high-risk individuals (Jornet et al., 2015). As indicated by the vicious cycle for DA (Berggren et al., 1984), anxiety, fear and avoidance behaviour to seek dental care can lead to poor oral health, reduced OHQoL and subsequently the feeling of inferiority and social isolation (Figure 5-1).

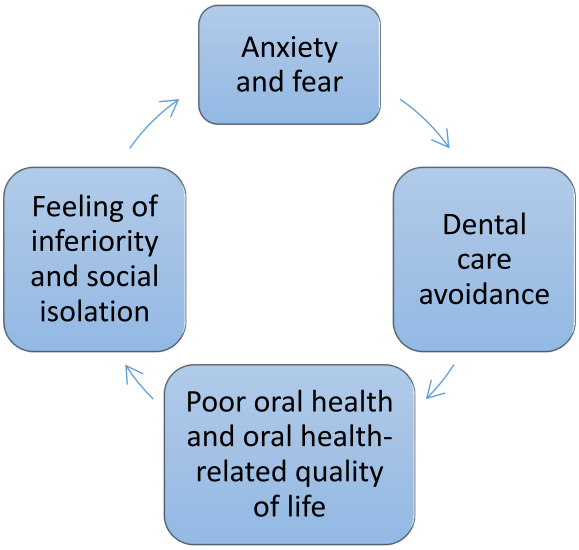


Figure 5-1 Berggren’s vicious cycle of dental anxiety.

Although the causal association cannot be determined for these variables (Carter et al., 2014), this association is likely to be attributed to psychological and psychiatric characteristics (e.g. neurotic disorders) and possibly higher rates of untreated oral disease in the affected groups (McGrath et al., 2004). DA is commonly evaluated using the Modified Dental Anxiety Scale (MDAS) which is preferred for use over the Corah’s scale (Corah, 1969) as the former measures the anaesthesia-related anxiety along with other items (Humphris et al., 1995). MDAS showed excellent reliability (Cronbach’s α) for the total scale among a cohort of UK public population adults (Humphris et al., 2013) [α=0.91] and Australian dental clinic attendants (Caltabiano et al., 2018) [α=0.89]. Also, its cross-cultural validation echoed the excellent reliability of the original version in a dental cohort of patients in Greece [α=0.90 and 0.92] (Coolidge et al., 2008) and good reliability in students aged 12-15 in Saudi [α=0.84] (Alamri et al., 2019) as well as the general population in Spain [α=0.83] (Coolidge et al., 2010). With the majority of the present studies being focused on dental care and the general population, there is no available study that specifically assessed DA using MDAS for patients with OPMDs or OED.

Using MDAS was deemed essential to assess the dental anxiety and dental pain-related perception which were considered barriers of seeking help among individuals with suspicious oral symptoms (Scott et al., 2009a) and at high risk of oral cancer (Dodd et al., 2008), respectively. For instance, the former can be investigated with items such as *'if you went to your dentist tomorrow, how would you feel'*. Whereas another item, ‘*if you are about to have a local anaesthetic injection to your gum’*, could be used to assess the perception toward dental pain (Humphris et al., 1995).

With the possible link found between both of anxiety and depression and OHQoL, the shortened form of the 49-item Oral Health Impact Profile (OHIP-14) (Slade et al., 1994) was used along with HADS to investigate these attributes in a cohort of patients with stomatological diseases (Llewellyn et al., 2003). This well-recognised OHQoL instrument in oral medicine research (Ni Riordain et al., 2010) has been adapted in different languages [e.g. Brazilian (Oliveira et al., 2005) and Chinese (Wong et al., 2002)], patients’ populations [e.g. those attending the outpatient oral medicine clinics (Llewellyn et al., 2003) and women with or at higher risk to HIV (Mulligan et al., 2008)] and oral mucosal diseases [e.g. Behçet’s disease (Mumcu et al., 2006) and OLP (Heffernan et al., 2007)]. In patients with oral diseases, OHIP-14 showed an excellent Cronbach’s α in two UK-based clinical studies of OLP [α=0.90] (Hegarty et al., 2002) and stomatological disorders including oral lichen planus [α=0.88] (Llewellyn et al., 2003). Both of these two studies found that patients with oral diseases (and oral lichen planus) had worse OHQoL and higher burden related to oral health than the general population.

Whether these previous findings on anxiety and depression, DA and OHQoL on patients and general populations would be similar in patients diagnosed with OED, which carries a long-term increased risk of malignant transformation to mouth cancer (Iocca et al., 2019), remains unknown due to the lack of studies that specifically assess these symptoms with relevance to OED. Thus, the present study aims, by using specific self-reported instruments, to assess the levels and prevalence of general anxiety and depression, dental anxiety and OHQoL among a UK cohort of patients with OED. Secondary objectives include identifying the demographics (e.g. age, gender, ethnicity, education and employment status) and clinical variables (e.g. number of associated general and conditions, number of medications, number of biopsies which showed OED, number of sites affected by OED, time since the first diagnosis, associated oral disorder/s and grading of OED) that can affect these levels. Thirdly, to evaluate the relationships within the instruments' scales and subscales.

5.2. Methods

This was a cross-sectional and secondary analysis of the data collected from the development and validation of the Oral Epithelial Dysplasia Information Needs Questionnaire (ODIN-Q) study [Chapter 3].

5.2.1. Study eligibility criteria and measures

The recruited participants of the ODIN-Q study (Chapter 3 and Appendix 4-7) were also asked to complete the following validated instruments:

- HADS
    - This 14-item instrument includes seven items on each of anxiety (HADS-A) and depression (HADS-D) subscales and rated by a four-point scale (0 to 3) that is based on the context of a question (Zigmond et al., 1983).
    - *Categorisation and cut-off scores* (Zigmond et al., 1983, Schellekens et al., 2016, Wiriyakijja et al., 2020):
        - The sum scores of both subscales were considered non-cases (0-7), doubtful (8-10) and definitive (11-21).
        - The total score for each subscale lies between 0 and 21 that collectively lead to an overall rating between 0-42.
        - The cut-off score of 8 for subscales (HADS-A and HADS-D) and 15 for the total scale (HADS-T) indicate the presence of anxiety/depression and emotional distress symptoms, respectively.

- The Modified Dental Anxiety Scale (MDAS)
    - This 5-item instrument is scored by 5-point scale (not anxious=1, extremely anxious=5) and has a total cut-off score of 19, which indicates the need for further management (Humphris et al., 1995).

- Oral Health Impact Profile (OHIP-14)

  - This includes 14 items under seven domains [functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap] and rated by 5-point severity scale (from never=0 to very often=4)
  - Scoring and cut-off:
    - The severity is proportional to the total score, which ranges between 0 and 56.
    - Although no ceiling or cut-off level available for OHIP-14, it has been suggested that an individual who indicates one or more selections for fairly or very often would be considered as a case (Tsakos et al., 2012).

5.2.2. Data analyses and representation

Data representation was performed using a proforma of Microsoft Excel (version 16.26). Data was transferred to IBM SPSS Statistics software (version 22.0) to perform the analytical tests. The frequency and descriptive analyses (mean, median, standard deviation and percentages) were calculated for each item, subscale and scale. The skewness of scores was determined to assess the degree of deviation from the median (i.e. normal distribution) (Scott et al., 2005) whereas kurtosis values were used to determine the peakedness or flatness of this deviation (Hair et al., 1998).

To assess the relationships between the assessed variables, a selection of a test was based on the type of dependent variable [continues numeric, binary and ordinal] (Hair et al., 1998, Heisler et al., 2003, Olssøn et al., 2005, Elkin et al., 2007). Based on the Shapiro-Wilk test (Shapiro et al., 1965), the instruments' scores were not normally distributed ($p < 0.05$). Therefore, the Spearman's rho coefficient was used to assess the correlations between and within the instruments (HADS, MDAS and OHIP-14 scales and subscales) and the respondents' categorical data (Zigmond et al., 1983, Ni Riordain et al., 2016, Yang et al., 2018a). These included the age groups based on 5-year interval and degree of OED. Results were interpreted as low [0.20-0.40], moderate [0.40-0.70] or high [>0.70] (Guilford, 1950). Furthermore, the relationship between the instruments' responses [scores and categories] and patients' demographic and clinical characteristics were assessed using the stepwise linear and ordinal and multinomial logistic regression analyses.

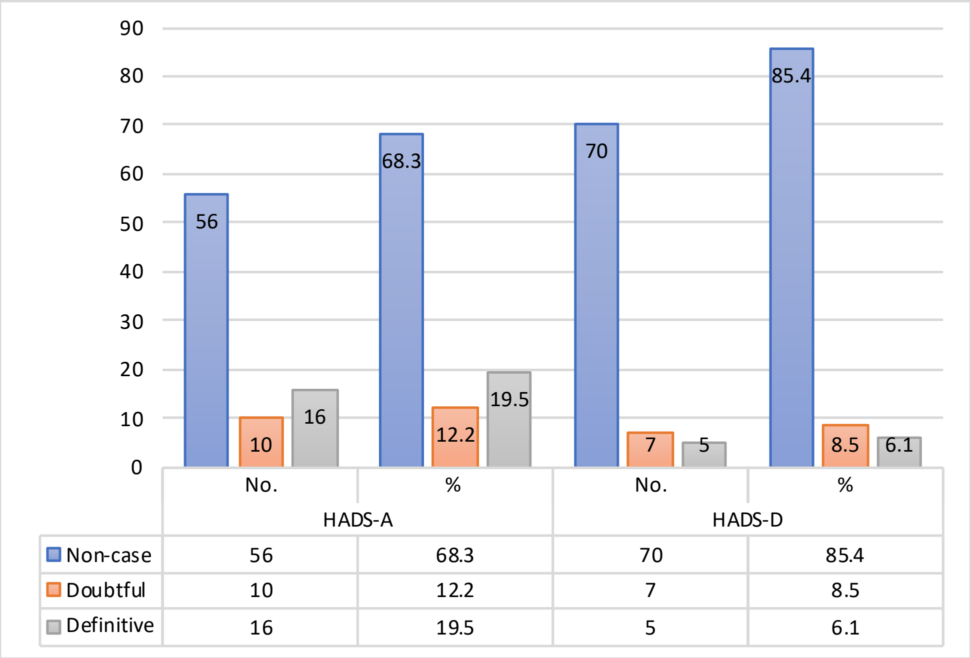
Cronbach's alpha was calculated for the assessed scales and subscales to assess their inter-item correlation (internal consistency). The results were interpreted as excellent (>.90), good (>0.80), acceptable (>0.70), questionable (>0.60), poor (>0.50) and unacceptable (<0.50) (Mallery et al., 2003, Cunningham et al., 2013). All tests were of two-tale and considered of statistical significance if the p-value is less than 0.05. Ethical approval was obtained as part of ODIN-Q study (Chapter 3).

5.3. Results

Eighty-two, out of the 86 participants, completed the study questionnaires. The responses from four participants [Study IDs 111, 132, 134 and 167] were not included from the analysis due to no response or multiple missing responses. The individual mean imputation method was followed for single missing responses to the HADS-9 and (Shrive et al., 2006, Eekhout et al., 2014). The demographic and clinical characteristics of the participants are shown in Appendix 7

5.3.1. Assessments of anxiety and depression using HADS in patients with OED

The descriptive analyses for the overall score (HADS-T) showed mean and median scores of 9.6 (±7.7) and 8.5 [HADS-A=4.5, HADS-D=3], respectively. This was reflected by a skewness value of 0.7, which indicated a positive distribution of the mean in relation to the normal distribution (median scores) as well as a negative kurtosis value of -0.25 which indicate a lightly flattened deviation. The categorisation of scores showed that only 16 (19%) and 5 (6%) of participants had definitive scores for anxiety and depression. Scores lied in the doubtful range were less than 20%, whereas those of non-case were of 68% or higher for both subscales (Figure 5-2).



	HADS-A No.	HADS-A %	HADS-D No.	HADS-D %
🟦 Non-case	56	68.3	70	85.4
🟧 Doubtful	10	12.2	7	8.5
▨ Definitive	16	19.5	5	6.1

Figure 5-2 The categorisation of HADS-A and HADS-D scores.

Based on the pre-defined cut-off scores of HADS scale and subscales, HADS-T scores indicated that only 22 out of the 82 participants (26%) presented a score reflecting emotional distress. Nevertheless, 25 (30%) reported the presence of anxiety and 13 (16%) of depression symptoms (Figure 5-3).

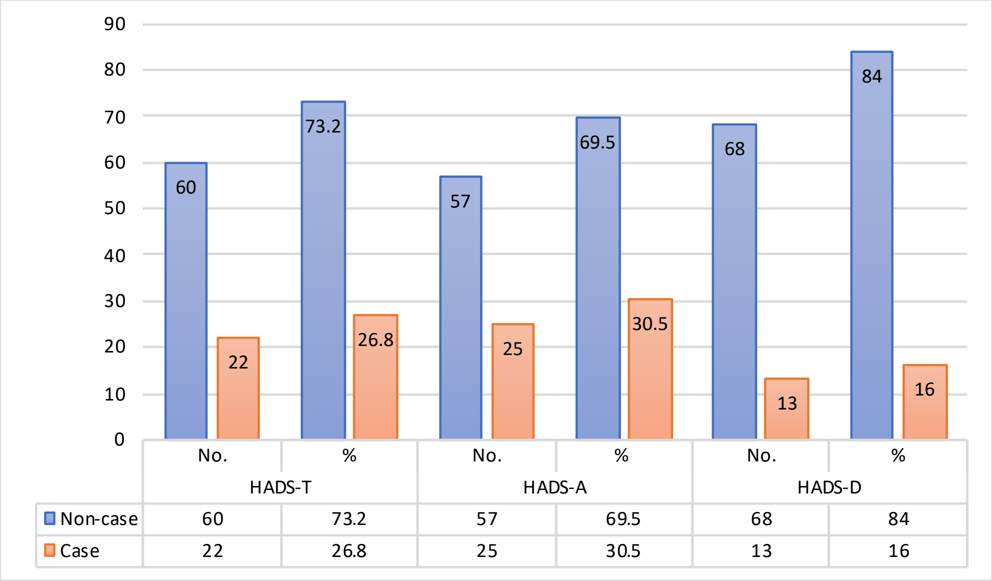


Figure 5-3 The distribution of participants' scores based on the cut-off scores (n=82).

Table 5.1 shows the analyses of items and subscales, which indicated a higher average mean score of anxiety items (5.6±4.6) [HADS-A] than of depression items (3.9±3.8) [HADS-D]. Of the former group, the highest mean scores were given to '*worrying thoughts go through my mind*' (1.02) and '*I feel tense or wound up*' (0.92) with more than 60% of respondents indicating occasional or frequent concerns related to these items. To a lesser degree, the highly concerning items also included '*I get a sort of frightened feeling like something awful is about to happen*' (0.86), '*I feel restless as if I have to be on the move*' (0.79) and '*I can sit at ease and feel relaxed*' (0.79).

Regarding depression items, the highest mean scores were noted with '*I feel as if I am slowed down*' (1) and '*I look forward with enjoyment to things'* (0.70). In contrast, more than 59% of respondents indicated no concerns related to '*I can enjoy a good book or* *radio or TV programme*' (0.30), '*I have lost interest in my appea*rance' (0.42), *'I feel cheerful'* (0.46), '*I can laugh and see the funny side of things'* (0.47) and '*I look forward with enjoyment to things*' (0.59).

Table 5-1 The descriptive analyses of HADS items, subscales and scale.

Item	**Mean**	**Median**	**Std. Deviation**	**Score distribution**								**Skewness**	**Kurtosis**
				0		1		2		3			
				No.	%	No.	%	No.	%	No.	%		
HADS1 - feeling tense	0.92	1	0.79	25	30.5	42	51.2	11	13.4	4	4.9	0.731	0.394
HADS3 - Frightening feeling	0.86	0	1.05	42	51.2	18	22	13	15.9	9	11	0.863	-0.591
HADS5 - worrying thoughts	1.02	1	0.99	30	36.6	29	35.4	14	17.1	9	11	0.647	-0.62
HADS7 - sit at ease	0.75	1	0.76	35	42.7	33	40.2	13	15.9	1	1.2	0.618	-0.442
HADS9 - butterflies in the stomach	0.62	0	0.76	42	51.2	32	39	5	6.1	3	3.7	1.278	1.604
HADS11 - feeling restless	0.79	1	0.76	33	40.2	34	41.5	14	17.1	1	1.2	0.543	-0.538
HADS13 - sudden panic	0.64	0.5	0.74	41	50	30	36.6	10	12.2	1	1.2	0.866	0.018
HADS-A score	5.63	4.5	4.65									0.754	-0.152
HADS2 - enjoy things	0.70	1	0.82	40	48.8	29	35.4	10	12.2	3	3.7	1.003	0.379
HADS4 - laugh/see funny side	0.47	0	0.72	53	64.6	20	24.4	8	9.8	1	1.2	1.388	1.147
HADS6 - cheerful	0.46	0	0.67	51	62.2	25	30.5	5	6.1	1	1.2	1.397	1.74
HADS8 - slowed down	1	1	0.91	27	32.9	35	42.7	13	15.9	7	8.5	0.691	-0.247
HADS10 - lost interest	0.42	0	0.77	59	72	13	15.9	8	9.8	2	2.4	1.747	2.174
HADS12 -excitement	0.59	0	0.85	49	59.8	21	25.6	8	9.8	4	4.9	1.368	1.068
HADS14 - enjoy leisure	0.30	0	0.53	60	73.2	19	23.2	3	3.7	0	0	1.575	1.63
HADS-D total	3.97	3	3.80									1.137	1.078
TOTAL HADS score	9.60	8.5	7.76									0.713	-0.255

5.3.2. *Assessments of dental anxiety using MDAS in patients with OED*

The descriptive analyses of MDAS scores showed a mean total score of 9.48 (±4.46) out of the overall score of 20. This was slightly higher than the median value of 8. These variations were also illustrated by the difference between the highest and lowest total scores of 25 and 5, respectively. Based on the cut-off score of 19, only three participants (3.7%) exceeded this level and therefore considered as dentally anxious. However, there were 9 participants (10%) who had scores that were at the borderline level (Figure 5-4).

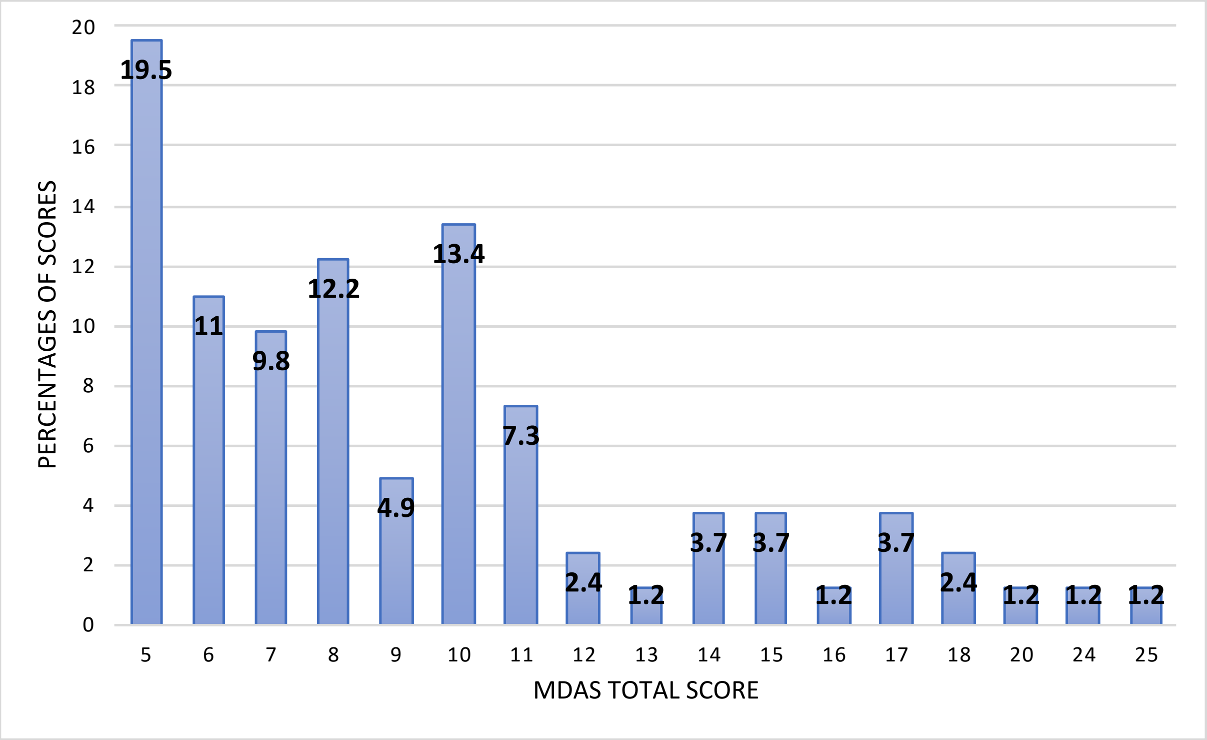


Figure 5-4 The distribution of sum MDAS scores by percentages.

The analyses of the mean scores of each item indicated a relatively high level of DA related to MDAS-3, '*if you were about to have a tooth drilled* '(2.26) and MDAS-5, '*if you were about to have a local anaesthetic injection in your gum*' (2.23). In comparison, the remaining three items [MDAS-1, 2 and 4] were given lower scores; '*if you went to your dentist for treatment tomorrow*' (1.69), '*if you were sitting in the waiting room*' (1.69) and '*if you were about to have your teeth scaled and polished*' (1.59), respectively (Figure 5-5).

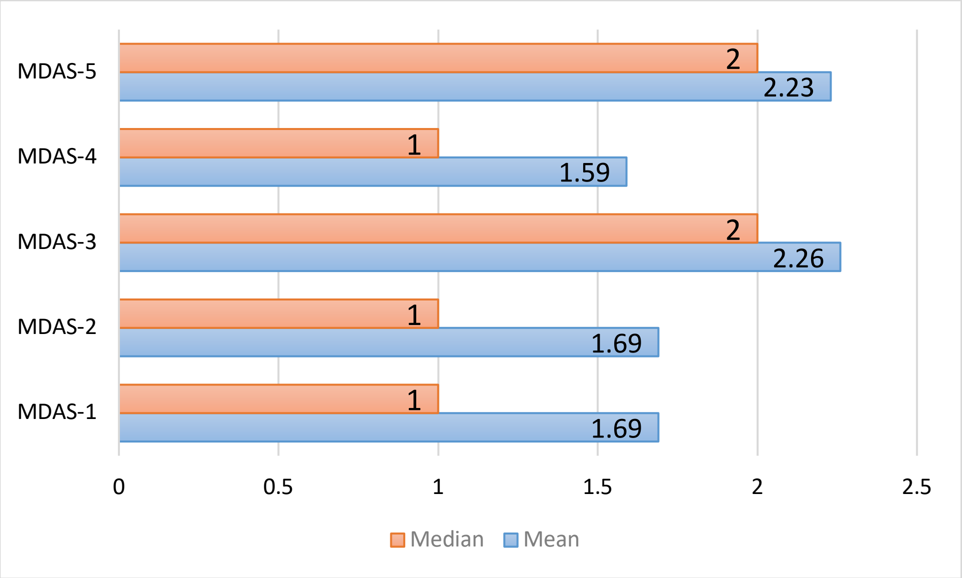


Figure 5-5 The mean and median scores for MDAS (n=5).

Table 5-2 shows the number and percentages of responses to each MDAS item which mirrored their mean scores. For instance, 56 (68%) and 57 (69%) of participants had some DA as indicated by MDAS-3 and MDAS-5, respectively. Similarly, more than 13% of them were very or extremely anxious with regards to these items. In contrast, no anxiety was noted among more than half of the respondents toward MDAS-4 (62%) and both MDAS-1 and 2 (57%).

Table 5-2 Number and percentages of responses to each MDAS item (n=5).

Item	Score distribution									
	Not Anxious		Slightly Anxious		Fairly Anxious		Very Anxious		Extremely Anxious	
	No.	%	No.	%	No.	%	No.	%	No.	%
1.Went to the dentist for treatment tomorrow	47	57.3	21	25.6	8	9.8	4	4.9	2	2.4
2. Sitting in the waiting room	47	57.3	21	25.6	8	9.8	4	4.9	2	2.4
3. About to have a tooth drilled	26	31.7	28	34.1	13	15.9	10	12.2	5	6.1
4. About to have the teeth scaled and polished	51	62.2	20	24.4	6	7.3	3	3.7	2	2.4
5. About to have a local anaesthetic injection in the gum, above an upper back tooth	25	30.5	30	36.6	15	18.3	7	8.5	5	6.1

5.3.3. Assessments of oral health-related quality of life using OHIP-14 among patients with OED

Based on the total score of 56 for OHIP-14, the analyses indicated a broad range of scores among respondents that skewed the mean score of (11.5 ±10.5) in the right to the median (8.5). This variation was explained by the 75th percentile of 21 and 13 (16%) of participants presenting a total score of zero compared to 21 (25%) who scored above 20. The remaining scores were in the range between 1 to 10 (44%) and 11 to 21 (23%) (Figure 5-6).

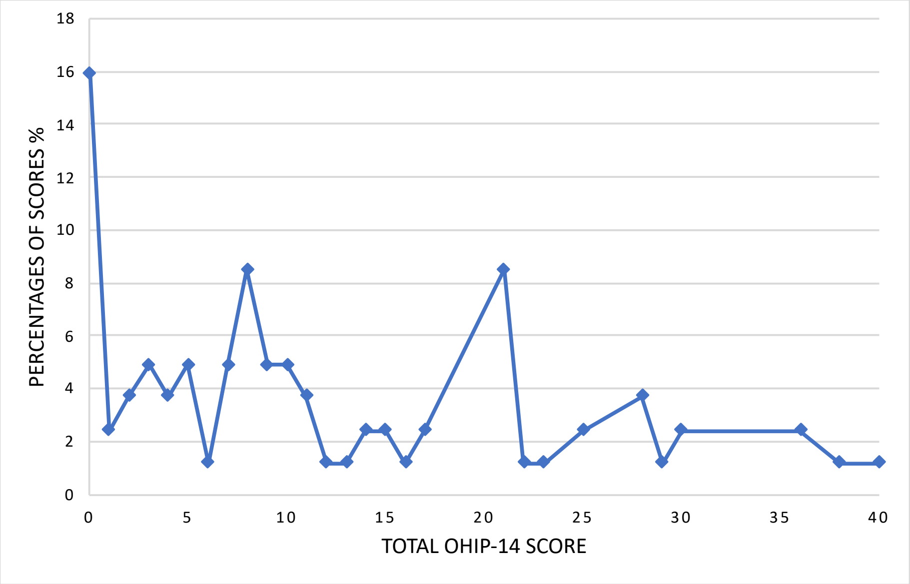


Figure 5-6 The distribution of the total OHIP-14 scores by percentages.

The highest scored domain for OHIP-14 was the physical pain which included the highest scored items as well; *'have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?'* (1.59) and *'have you had painful aching in your mouth?'* (1.40). This was followed by the psychological discomfort domain and its two items; *'have you felt tense because of problems with your teeth, mouth or dentures?'* (1.25) and *'have you been self-conscious because of your teeth, mouth or dentures?'* (1.24) (Figure 5-7).

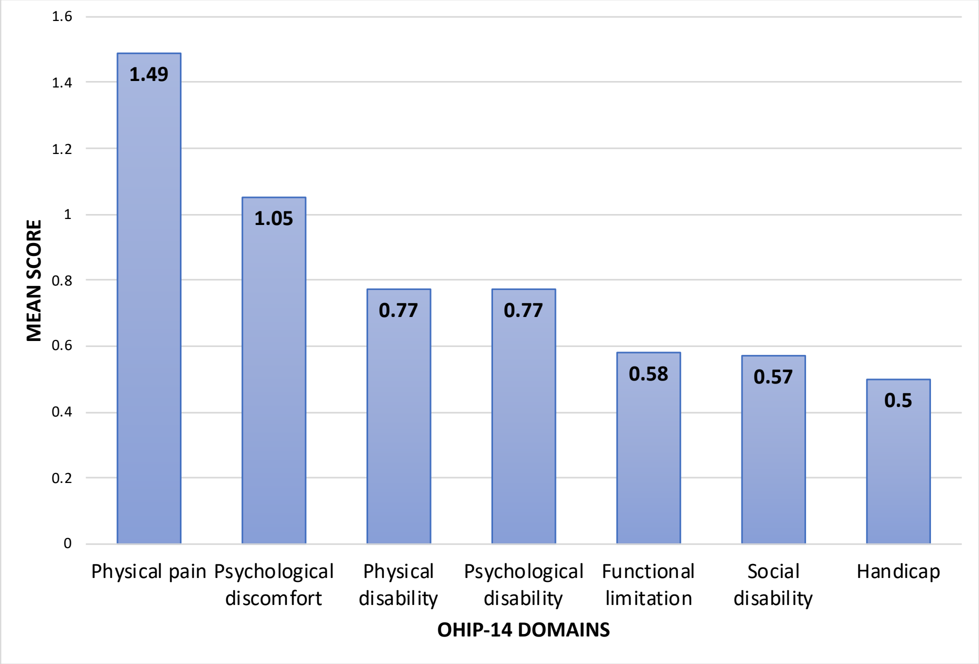


Figure 5-7 The mean scores of OHIP-14 domains (n=7).

In contrast, the lowest scored domain was the handicap with its item, '*have you been totally unable to function because of problems with your teeth, mouth or dentures?'* obtaining the lowest mean score of 0.25. Correspondingly, 95% of participants had never or hardly ever concerns towards it. Other low scored items that the majority of participants answered with 'never' and 'hardly every' were as follows; '*have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?*' (86%), '*have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?*' (85%), *'have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?*' (80%), '*have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?*' (75%) and *'have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?'* (74%) (Table 5-3).

Table 5-3 The descriptive analyses of OHIP-14 items (n=14).

Item	**Mean**	**Median**	**Std. Deviation**	**Score distribution**									
				Never		Hardly ever		Occasionally		Fairly often		Very often	
				No.	%	No.	%	No.	%	No.	%	No.	%
1.Trouble pronouncing any words	0.47	0	0.94	61	74.4	9	11	8	9.8	2	2.4	2	2.4
2. Sense of taste has worsened	0.70	0	1.15	54	65.9	11	13.4	7	8.5	7	8.5	3	3.7
3. Painful aching in the mouth	1.40	1	1.38	32	39	14	17.1	14	17.1	15	18.3	7	8.5
4. Uncomfortable to eat any foods	1.59	2	1.40	29	35.4	8	9.8	20	24.4	17	20.7	8	9.8
5. Been self-conscious	1.08	1	1.24	39	47.6	14	17.1	16	19.5	9	11	4	4.9
6. Felt tense	1.02	0	1.25	43	52.4	10	12.2	17	20.7	8	9.8	4	4.9
7. Diet been unsatisfactory	0.79	0	1.19	52	63.4	8	9.8	12	14.6	7	8.5	3	3.7
8. Had to interrupt meals	0.75	0	1.00	47	57.3	14	17.1	15	18.3	6	7.3	0	0
9. Difficult to relax	0.76	0	1.04	47	57.3	15	18.3	13	15.9	6	7.3	1	1.2
10.Been a bit embarrassed	0.78	0	1.08	48	58.5	13	15.9	14	17.1	5	6.1	2	2.4
11. Been a bit irritable with other people	0.69	0	1.05	53	64.6	8	9.8	15	18.3	5	6.1	1	1.2
12. Had difficulty doing the usual jobs	0.46	0	0.81	58	70.7	13	15.9	8	9.8	3	3.7	0	0
13. Felt that life in general was less satisfying	0.76	0	1.11	50	61	11	13.4	13	15.9	6	7.3	2	2.4
14. Been totally unable to function	0.25	0	0.64	67	81.7	11	13.4	3	3.7	0	0	1	1.2
Total score	11.57	8.5	10.51										

Furthermore, the arbitrary cut-off suggested that 34 of the respondents (41.5%), who chose one or more of 'fairly often' or 'very often' responses, had problems in the daily life due to their oral health. The number of these selections ranged from 1 to 11 for each respondent.

5.3.4. Correlations between instruments and the patient's characteristics

The Spearman's rho test showed a significant, but weak negative correlation between the older age group and both of HADS-9, '*I get a sort of frightened feeling like 'butterflies in the stomach*' [r = -.244, p = 0.027] and OHIP-10, *'have you been a bit embarrassed because of problems with your teeth, mouth or dentures?*' [r = -.219, p = 0].

Linear regression analyses showed that the number of associated oral conditions was a significant predictor for OHIP-14 total scores; with every additional condition, there was a chance of 0.032 increase on OHIP-14 score (t = 2.31, p = .024). Similarly, the number of medications was also a significant predictor for the HADS-D score; with every additional medication, there was 0.29 increase on HADS-D score (t = 2.28, p = .025). In contrast, the sum score of the amount of information received subscale of ODIN-Q, age and number of OED lesions were none of significance. No significant correlation was found between the amount of information received subscale of ODIN-Q and the total scores of HADS, MDAS and OHIP-14.

The binary logistic regression showed that being symptomatic was a predictor for having higher (worse) scores for HADS-6 (*feel cheerful*) with an odds ratio (OR) of 5.76 (p = .021, 95% CI: 1.29-25.59). Whereas the history of cancer and the degree of OED were not of significance using the previous test and ordinal logistic regression, respectively. Similarly, the level of information needs (met or unmet needs) was not significantly related to the items of HADS, MDAS and OHIP-14.

Multinomial logistic regression showed that none of the patient's demographics (gender, ethnicity, education, employment status, smoking and alcohol drinking) and clinical variables (associated oral condition and category of years since being diagnosed) was of significance.

5.3.5. *Correlations within and between the instruments*

The analyses using Spearman's rho coefficients among and between HADS items and those of other instruments showed a high correlation between '*worrying thoughts'* (HADS-5) and '*sudden feelings of panic'* (HADS-13) [*r* = .746, *p* = 0.00]. A similar level of correlation was found between '*still enjoy the things I used to enjoy'* (HADS-2) and '*look forward with enjoyment to things'* (HADS-12) [r = .716, p = 0.00].

In contrast, a notable moderate relationship (>.66) were observed between the following; '*frightening feeling'* (HADS-3) and both of '*worrying thoughts'* (HADS-5) [*r* = .691, *p* = 0.00] and '*sudden panic'* (HADS-13) [*r* = .684, *p* = 0.00] in one side and between '*worrying thoughts'* (HADS-5) and both of '*feel cheerful'* (HADS-6) [*r* = .668, *p* = 0.00] and '*sit at ease and feel relaxed'* (HADS-7) [*r* = .684, *p* = 0.00] on the other side (Table 5-4). At the subscale level, a high correlation was found between HADS-A and HADS-D based on the scores [*r* = .741, *p* = 0.01] as well as between the degree of severity of HADS-A and both of the presence or absence of depression (HADS-D) [*r* = .907, *p* = 0.00] and the emotional distress (HADS-T) [*r* = .716, *p* = 0.00].

Table 5-4 Spearman’s rho values for the Hospital Anxiety and Depression Scale (HADS).

Item	HADS -1	HADS -3	HADS -5	HADS -7	HADS -9	HADS -11	HADS -13	HADS -2	HADS -4	HADS -6	HADS -8	HADS -10	HADS -12	HADS -14
HADS-1		.656**	.549**	.657**	.447**	.345**	.629**	.334**	.507**	.464**	.324**	.256*	.382**	.429**
HADS-3	.656**		.691**	.655**	.557**	.262*	.684**	.365**	.497**	.528**	.317**		.462**	.467**
HADS-5	.549**	.691**		.684**	.639**	.434**	.746**	.502**	.539**	.668**	.434**	.258*	.588**	.461**
HADS-7	.657**	.655**	.684**		.457**	.482**	.590**	.496**	.485**	.626**	.410**	.326**	.579**	.472**
HADS-9	.447**	.557**	.639**	.457**		.346**	.670**	.366**	.439**	.438**	.417**	.273*	.465**	.396**
HADS-11	.345**	.262*	.434**	.482**	.346**		.349**	.289**	.322**	.323**	.329**	.409**	.394**	.311**
HADS-13	.629**	.684**	.746**	.590**	.670**	.349**		.366**	.428**	.514**	.391**	.310**	.510**	.475**
HADS-2	.334**	.365**	.502**	.496**	.366**	.289**	.366**		.457**	.496**	.538**	.294**	.716**	.349**
HADS-4	.507**	.497**	.539**	.485**	.439**	.322**	.428**	.457**		.526**	.332**	.311**	.529**	.326**
HADS-6	.464**	.528**	.668**	.626**	.438**	.323**	.514**	.496**	.526**		.458**	.385**	.562**	.496**
HADS-8	.324**	.317**	.434**	.410**	.417**	.329**	.391**	.538**	.332**	.458**		.354**	.490**	.291**
HADS-10	.256*		.258*	.326**	.273*	.409**	.310**	.294**	.311**	.385**	.354**		.389**	.278*
HADS-12	.382**	.462**	.588**	.579**	.465**	.394**	.510**	.716**	.529**	.562**	.490**	.389**		.377**
HADS-14	.429**	.467**	.461**	.472**	.396**	.311**	.475**	.349**	.326**	.496**	.291**	.278*	.377**	
MDAS 1	.315**	.279*	.331**	.272*	.345**	.289**	.362**		.218*			.279*		.280*
MDAS 2	.323**	.324**	.302**	.287**	.354**		.378**	.224*	.261*					.273*
MDAS 3		.250*	.219*	.295**	.335**	.346**	.343**		.227*			.268*		.267*
MDAS 4														
MDAS 5		.270*	.329**	.279*	.382**		.437**							.299**
OHIP-1			.241*		.383**								.247*	.221*
OHIP-2					.346**			.240*	.318**	.232*	.268*		.284**	
OHIP-3	.309**	.364**	.325**	.434**	.380**		.417**		.415**	.379**	.330**	.278*	.368**	
OHIP-4	.314**	.315**	.366**	.431**	.390**	.264*	.451**	.280*	.483**	.423**	.409**	.224*	.479**	.242*
OHIP-5					.236*									

OHIP-6	.363**	.492**	.454**	.501**	.498**	.306**	.459**	.333**	.489**	.404**	.241*	.221*	.414**	.289**
OHIP-7		.276*	.256*	.341**	.328**			.252*	.456**	.305**	.339**		.316**	
OHIP-8	.259*	.342**	.413**	.475**	.382**	.304**	.322**	.316**	.431**	.430**	.310**		.399**	.327**
OHIP-9	.544**	.513**	.495**	.561**	.546**	.343**	.446**	.343**	.457**	.451**	.295**		.409**	.304**
OHIP-10	.289**	.329**	.362**	.263*	.332**		.324**		.226*	.238*				
OHIP-11	.437**	.401**	.426**	.425**	.401**	.234*	.416**	.271*	.545**	.516**	.255*	.268*	.411**	.272*
OHIP-12	.393**	.422**	.445**	.460**	.424**	.286**	.382**	.305**	.612**	.461**	.320**		.471**	
OHIP-13	.392**	.434**	.517**	.569**	.400**	.378**	.418**	.408**	.535**	.441**	.318**		.533**	
OHIP-14	.247*	.343**	.373**	.350**	.327**	.273*	.430**	.366**	.373**	.382**	.262*		.461**	

MDAS, the Modified Dental Anxiety Scale; OHIP-14, Oral Health Impact Profile.
* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

When MDAS items were compared to among each other and with other scales, the only high correlation was found between the DA related to going to the dentist for treatment tomorrow (MDAS-1) and sitting in the waiting room (MDAS-2) [*r* = .853, *p* = 0.00]. Moderate correlations were present between all MDAS items, MDAS-1 and both of '*been self-conscious'* (OHIP-5) [*r* = .433, *p* = 0.00] and '*been a bit embarrassed'* (OHIP-10) [*r* = .439, *p* = 0.00]. A similar level of correlation also existed between the local anaesthetic injection-related anxiety (MDAS-5) and both of '*sudden feelings of panic'* (HADS-13) [*r* = .437, *p* = 0.00] and '*feel cheerful'* (OHIP-6) [*r* = .405, *p* = 0.00] (Table 5-5).

Table 5-5 Spearman's rho values for the Modified Dental Anxiety Scale (MDAS).

Items	MDAS-1	MDAS-2	MDAS-3	MDAS-4	MDAS-5
HADS-1	.315**	.323**			
HADS-3	.279*	.324**	.250*		.270*
HADS-5	.331**	.302**	.219*		.329**
HADS-7	.272*	.287**	.295**		.279*
HADS-9	.345**	.354**	.335**		.382**
HADS-11	.289**		.346**		
HADS-13	.362**	.378**	.343**		.437**
HADS-2		.224*			
HADS-4	.218*	.261*	.227*		
HADS-6					
HADS-8					
HADS-10	.279*		.268*		
HADS-12					
HADS-14	.280*	.273*	.267*		.299**
MDAS 1		.853**	.633**	.534**	.471**
MDAS 2	.853**		.632**	.655**	.550**
MDAS 3	.633**	.632**		.553**	.542**
MDAS 4	.534**	.655**	.553**		.461**
MDAS 5	.471**	.550**	.542**	.461**	
OHIP-1				.251*	.326**

OHIP-2					
OHIP-3					.228*
OHIP-4					
OHIP-5	.433**	.361**	.284**	.257*	.224*
OHIP-6	.331**	.369**	.379**	.337**	.405**
OHIP-7					
OHIP-8			.230*	.249*	.307**
OHIP-9	.244*	.252*			.352**
OHIP-10	.439**	.356**	.324**	.282*	.255*
OHIP-11					
OHIP-12					
OHIP-13					.242*
OHIP-14					

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).

The analyses within OHIP-14 items showed a high correlation between '*painful aching in the mouth'* (OHIP-3) and '*been uncomfortable to eat any foods'* (OHIP-4) [r=.718, p = 0.0] as well as between '*been difficult to relax'* (OHIP-9) and '*felt that life in general was less satisfying'* (OHIP-13) [r = .702, p = 0.0].

Furthermore, a notable moderate relationship between '*had to interrupt meals'* (OHIP-8) and the following items; '*felt tense'* (OHIP-6) [r = .698 , p = 0.0], '*difficult to relax'* (OHIP-9) [r = .677, p = 0.0], '*felt that life in general was less satisfying'* (OHIP-13) [r = .668, p = 0.0] and '*been uncomfortable to eat any foods'* (OHIP-4) [r = .660 , p = 0.0]. Similar levels were also observed between OHIP-9 and both of OHIP-6 [r = .664, p = 0.0] and OHIP-8 [r = .677, p = 0.0]. Also, between '*been a bit irritable with other people;* (OHIP-11) and both of '*difficulty doing the usual jobs;* (OHIP-12) [r = .676, p = 0.0] and '*felt that life in general was less satisfying'* (OHIP-13) [r = .689, p = 0.0] (Table 5-6).

Table 5-6 Spearman's rho values for the Oral Health Impact Factor (OHIP-14).

Items	OHIP-1	OHIP-2	OHIP-3	OHIP-4	OHIP-5	OHIP-6	OHIP-7	OHIP-8	OHIP-9	OHIP-10	OHIP-11	OHIP-12	OHIP-13	OHIP-14
HADS-1			.309**	.314**		.363**		.259*	.544**	.289**	.437**	.393**	.392**	.247*
HADS-3			.364**	.315**		.492**	.276*	.342**	.513**	.329**	.401**	.422**	.434**	.343**
HADS-5	.241*		.325**	.366**		.454**	.256*	.413**	.495**	.362**	.426**	.445**	.517**	.373**
HADS-7			.434**	.431**		.501**	.341**	.475**	.561**	.263*	.425**	.460**	.569**	.350**
HADS-9	.383**	.346**	.380**	.390**	.236*	.498**	.328**	.382**	.546**	.332**	.401**	.424**	.400**	.327**
HADS-11				.264*		.306**		.304**	.343**		.234*	.286**	.378**	.273*
HADS-13			.417**	.451**		.459**		.322**	.446**	.324**	.416**	.382**	.418**	.430**
HADS-2		.240*		.280*		.333**	.252*	.316**	.343**		.271*	.305**	.408**	.366**
HADS-4		.318**	.415**	.483**		.489**	.456**	.431**	.457**	.226*	.545**	.612**	.535**	.373**
HADS-6		.232*	.379**	.423**		.404**	.305**	.430**	.451**	.238*	.516**	.461**	.441**	.382**
HADS-8		.268*	.330**	.409**		.241*	.339**	.310**	.295**		.255*	.320**	.318**	.262*
HADS-10			.278*	.224*		.221*					.268*			
HADS-12	.247*	.284**	.368**	.479**		.414**	.316**	.399**	.409**		.411**	.471**	.533**	.461**
HADS-14	.221*			.242*		.289**		.327**	.304**		.272*			
MDAS 1					.433**	.331**			.244*	.439**				
MDAS 2					.361**	.369**			.252*	.356**				
MDAS 3					.284**	.379**		.230*		.324**				
MDAS 4	.251*				.257*	.337**		.249*		.282*				
MDAS 5	.326**		.228*		.224*	.405**		.307**	.352**	.255*			.242*	
OHIP-1				.294**		.261*	.238*	.446**	.280*			.279*	.221*	
OHIP-2			.315**	.424**		.227*	.507**	.330**	.238*		.253*	.360**	.314**	.258*
OHIP-3		.315**		.718**		.384**	.484**	.562**	.499**		.499**	.419**	.552**	.453**

OHIP-4	.294**	.424**	.718**			.564**	.496**	.660**	.598**	.288**	.597**	.519**	.626**	.506**
OHIP-5						.644**		.426**	.344**	.629**	.304**	.320**	.299**	
OHIP-6	.261*	.227*	.384**	.564**	.644**		.430**	.698**	.664**	.652**	.618**	.576**	.616**	.334**
OHIP-7	.238*	.507**	.484**	.496**		.430**		.532**	.506**	.259*	.444**	.566**	.630**	.379**
OHIP-8	.446**	.330**	.562**	.660**	.426**	.698**	.532**		.677**	.540**	.561**	.545**	.668**	.365**
OHIP-9	.280*	.238*	.499**	.598**	.344**	.664**	.506**	.677**		.482**	.644**	.612**	.702**	.446**
OHIP-10				.288**	.629**	.652**	.259*	.540**	.482**		.458**	.345**	.473**	
OHIP-11		.253*	.499**	.597**	.304**	.618**	.444**	.561**	.644**	.458**		.676**	.689**	.465**
OHIP-12	.279*	.360**	.419**	.519**	.320**	.576**	.566**	.545**	.612**	.345**	.676**		.655**	.533**
OHIP-13	.221*	.314**	.552**	.626**	.299**	.616**	.630**	.668**	.702**	.473**	.689**	.655**		.611**
OHIP-14		.258*	.453**	.506**		.334**	.379**	.365**	.446**		.465**	.533**	.611**	

Regarding the reliability coefficients of the assessed scales and subscales, excellent or near excellent Cronbach's alpha values were found with HADS, MDAS, and OHIP-14. Although the majority of subscales were of acceptable levels, the functional limitations and psychological disability domains of OHIP-14 presented a relatively low level of scores (Table 5-7).

Table 5-7 Cronbach's α of the instruments' scales and subscales.

Scale or subscale	Cronbach's α value	Interpretation
HADS	.914	Excellent
HADS-A	.896	Excellent/good
HADS-D	.836	Good
MDAS	.892	Excellent/good
OHIP-14	.907	Excellent
Functional limitations	.396	Unacceptable
Physical pain	.840	Good
Psychological discomfort	.771	Acceptable
Physical disability	.699	Questionable/acceptable
Psychological disability	.581	Poor
Social disability	.722	Acceptable
Handicap	.684	Questionable

5.4. Discussion

In a cohort of 82 patients diagnosed with OED, the present study used validated patient-reported outcome measures to assess of the anxiety and depression, DA levels and OHQoL in terms of presence or absence of attributable symptoms, severity and prevalence rates based on the predefined cut-off scores for each instrument. These were evaluated for correlations with the patients' demographic and clinical characteristics and presented several significant findings. For instance, the prevalence of anxiety, depression and emotional symptoms in the present sample was at 30% for anxiety (HADS-A), 16% for depression (HADS-D) and 26% for emotional distress (HADS-T). These rates are generally similar to those of a UK-based study of patients with oral lichen planus that reported prevalence rates 39%, 20% and 27%, respectively (Wiriyakijja et al., 2020). Similar levels were also found among those attending general practice in Norway with 28% for anxiety and 18% for depression (Olssøn et al., 2005). However, these levels were higher than the rates found among a non-clinical sample in the UK of 12.6% and 3.6% for anxiety and depression using HADS, respectively (Crawford et al., 2001). Similarly, these were relatively higher than those reported with 14 women newly diagnosed with a pre-malignant condition elsewhere in the body (vulval intraepithelial neoplasia) with 17% of them indicated anxiety but none for depression (McFadden et al., 2009).

Furthermore, the present median scores for HADS-A (4.5) and HADS-D (3) were slightly high compared to those found in patients with pre-malignant neoplasms of the pancreas (4 and 2, respectively) (Verma et al., 2017). The two highest scored HADS items, '*Worrying thoughts go through my mind'* and '*I get a sort of frightened feeling like something awful is about to happen'* were also among the highest scored items in Wiriyakijja's study of oral lichen plans (Wiriyakijja et al., 2020). This might be predicted with OPMDs as several sources of distress and anxiety may present such as those related to initial symptoms, the uncertainty of the precise diagnosis, the referral process and the implication of the final diagnosis and/or any required treatment (Ndukwe et al., 2012, Lin et al., 2015, Renzi et al., 2015).

Regarding DA, the present analyses indicated that 3.7% of the respondents had high DA - which is much lower than the range of 8-11% found among population-based studies in the UK and China (Yuan et al., 2008, Humphris et al., 2009, Humphris et al., 2013). When respondents with borderline scores were included (10%), the prevalence rate was slightly higher in the present sample. Moreover, the mean overall score of MDAS [9.49±4.46] was similar to the mean found in new patients attending dental student clinics in Finland [9.44±3.91], Australia [10.76±5.06], UAE [10.90±4.28], but less than similar cohort in Ireland [12.40±5.98] (Humphris et al., 2000, Caltabiano et al., 2018). The previous study by Caltabiano et al. also found high scores among the study participants on the tooth being drilled (MDAS-3) and local anaesthetic injection (MDAS-5) with both of the scores to these items being increased among females compared to males. Although both items were the highest in the present study, however, separate analyses to compare the scores between males and females were not performed and therefore these findings cannot be validated presently.

There have been few comparative studies that assessed oral diseases using MDAS. Levin et al. (2018) used the 4-item Corah's anxiety scale to indicate higher DA levels in 3 items with 60 patients who had the diagnosis of aggressive periodontitis compared to 80 control subjects. In contrast to the present findings, the previous study indicated the highest scored item among both groups was the item related to going to the dental appointment tomorrow (Levin et al., 2018). Also, the instrument used in Levin's study does not, however, take in account assessing the anxiety related to the local anaesthetic, which presently found to be highly scored and significantly related to anxiety symptoms of the sudden feelings of panic and the psychological discomfort of OHQoL.

The assessments of OHQoL measured by OHIP-14 showed a median global score of 8.5 which was lower than the median noted among 97 patients with stomatological diseases and attending Oral Medicine outpatients' clinics (median = 11) and higher than the UK non-clinical population (median = 2) (Llewellyn et al., 2003). The Llewellyn's study also indicated worse levels of functional limitation and psychological disability domains of OHIP-14 than in a general population which is in line with the present findings. In contrast, the respondents of the present study had a lower mean global score (11 ± 10.5) than reported patients with aggressive periodontitis (13.75 ± 9.99), but higher than patients with no periodontal disease (Levin et al., 2018). When compared to previous studies of OPMDs and oral cancer, the present OHIP-14 score was notably higher than those found in a cohort of patients in Germany with oral leukoplakia (6.98±10.2), oral squamous cell carcinoma (8.81±8.6) or oral lichen planus (9.42±11.4) (Karbach et al., 2014).

The mean of all variables measured in the study (anxiety, depression, distress, DA and OHQoL) in the present study was positively skewed to the median, which indicated that some individuals had higher scores compared to most participants. Significant predictors for depressive symptoms in patients with oral lichen planus were the Asian ethnic group, no alcohol drinking and increased disease comorbidities (Wiriyakijja et al., 2020). None of these was found to be significant in the present study at subscale or scale levels. The only significant demographic variable was the older age group who had fewer concerns related to frightening feeling (anxiety) and 'been embarrassed because of problems in the mouth' (OHQoL). In contrast, clinical variables such as the number of oral conditions or problems and number of current medications were positively related to the total scores of OHIP-14 (OHQoL) and HADS-D (depression symptoms), respectively. However, these were not investigated in the previous study on patients with oral lichen planus (Wiriyakijja et al., 2020). A qualitative study on women with cervical dysplasia found an association between the increased experienced levels of anxiety with less knowledge about the disease, rather than the severity of its grade (Lee Mortensen et al., 2010). Nevertheless, the present study did not validate these results – the levels of anxiety symptoms were not related the level of IN or the OED grade.

There is very little known about the levels of general anxiety and depression, DA and OHQoL among individuals with potentially cancerous oral disease. Of note, significant correlations were found between the respondents' scores for HADS, MDAS and OHIP-14, which support the possibility of co-existence of these attributes. Scores of HADS (anxiety and depression symptoms) were highly correlated with those of OHIP-14 (OHQoL) than with MDAS (DA). Each item of HADS, MDAS and OHIP-14 had at least one significant correlation ($p > 0.05$) with items of other instruments except MDAS-4 (teeth being scaled and polished), which showed no significant correlations to any of HADS items (Table 5.5). Also, other MDAS items showed significant but relatively low correlations with other instruments compared to the correlations found between HADS (anxiety and depression symptoms) and OHIP-14 (OHQoL). On the contrary to the present study, MDAS-4 had significant relationships along with other MDAS items with all anxiety items of HADS (Yuan et al., 2008) and thus supported the hypothesis that the constructs of anxiety and DA are theoretically related.

In line with the present findings, Yang and colleagues compared HADS and OHIP-14 scores between patients with oral mucosal diseases and healthy control group in China and indicated significant correlations between OHQoL (OHIP-14) and both of anxiety (HADS-A) and depression symptoms (HADS-D) among those with oral lichen planus, recurrent aphthous ulcer and the control group (Yang et al., 2018a). The previous study found higher HADS and OHIP-14 scores, especially in the ulcer group than those of the healthy individuals. Also, correlations between OHIP-14 subscales and both of HADS-A and HADS-D were found to be significant in individuals with stomatological diseases but notably low especially between HADS-A and physical pain (Spearman's r = 0.043) and physical disability (r = 0.096) (Llewellyn et al., 2003). Although the present study did not assess the correlations on subscale level, however, items under the physical pain and disability domains of OHIP-14 showed slightly higher correlations with HADS-A items with lowest Spearman's rho was at .25 (Table 5.6). Nevertheless, another study on patients with oral lichen planus found no statistically significant correlation between HADS and OHIP-14 (Vilar-Villanueva et al., 2019). However, the performed analysis test (multiple correspondence test) used was different than what the present study used (Spearman's test).

The present study findings also support the vicious cycle presented for DA by Breggan (Figure 5.1) (Berggren et al., 1984). An Australian study has examined this model in a general population sample of more than 6000 individuals and found that increased dental fear was associated with delayed dental visits and poor self-reported oral health (Armfield et al., 2007). Similar findings were found by Locker who studied these variables among the general population in Canada and found that individuals with increased DA were likely to avoid dental visits and had compromised self-reported oral health (Locker, 2003). Moreover, Crofts-Barnes et al. (2010) showed a significant correlation between the scores of general and dental anxieties and those of quality of life. The findings of the present study also favour of these findings – anxiety toward going to the dental appointment tomorrow was relevant to been self-conscious and a bit embarrassed due to dental or oral problems. In a qualitative study on patients who high dental anxiety found the embarrassment to be related to lower self-esteem whereas the number of years for dental avoidance and tendency of mouth-hiding behaviour being predicted by the intensity of the embarrassment (Moore et al., 2004).

The increased prevalence of anxiety and depression in patients with chronic oral mucosal diseases (including the oral lichen planus) (Yang et al., 2018a) encourage clinicians to use HADS in the day-to-day clinical care of patients with OED to identify and predict those at higher probable risk of anxiety and/or depression and refer these to specialists for therapeutic intervention – when needed. Other research found poorer quality of life and OHQoL in patients with OPMDs, but not the OED (e.g. oral lichen planus, oral leukoplakia, discoid lupus erythematous), than healthy individuals (Liu et al., 2012) or those who had no chronic disease of the oral mucosa (Ni Riordain et al., 2016), respectively. Therefore, OHIP-14 can also help to identify those who have a higher impairment, caused by OED lesions or its associated OPMDs, on aspects of OHQoL such as physical and social disabilities, which found to be related to social isolation in patients with oral lesions (María-del-Carmen Villanueva-Vilchis et al., 2016). As with other quality of life instruments, OHIP-14 can also be useful to indicate the need for further care and to evaluate the effectiveness of treatments for OED (Sareen et al., 2005, Sanders et al., 2009).

Similarly, MDAS can be a helpful tool for clinicians and health care planners to present appropriate interventions for DA when needed to maintain regular attendance of screening and follow-up appointments and possibly encourage seeking professional help when worrisome symptoms arise in those who had previous oral suspicious lesions. Based on the severity of DA and treatment need, these interventions can include applying anxiety reduction techniques (e.g. presenting appropriate information, supporting the patient's control, trust and predictability of procedures), targeted pharmacological interventions (e.g. using sedatives such as nitrous oxide), providing coping techniques (e.g. relaxation and hypnosis) or referral to the clinical psychology or psychiatric medicine (De Jongh et al., 2005). Nevertheless, these instruments need to be carefully selected, tested and interpreted due to the inherited limitations related to its design and presentation, psychometric properties, clinical interpretability and generalisability of results (Boynton et al., 2004, Mokkink et al., 2010a).

Strengths and limitations

Strengths include assessing the anxiety and depression, DA and OHQoL in patients with OED for the first time. The present study also indicated which demographic and clinical characteristics were likely to influence these constructs, which can help clinicians to predict and early recognise patients who are likely to present these symptoms. Also, the significant correlations between the instruments presented further support to the previous research findings of studies on conditions other than the OED that suggested the associations between the studied constructs (Berggren et al., 1984, Llewellyn et al., 2003, Yuan et al., 2008, Yang et al., 2018a).

The study has some limitations, such as the relatively low sample size and a lack of control sample for comparisons and non-confirmed clinical diagnoses of anxiety, depression or DA. Also, there was a lack of meaningful benchmarks and minimal important difference level for scores (Tsakos et al., 2012), and a possible tendency to assess the attributes during a specified reference period (e.g. in the past week or year). Although the present analyses showed high internal consistency reliability for pre-validated instruments, the assessments of other important aspects of reliability (test-retest), validity (structural and criterion), responsiveness and interpretability were not performed.

5.5. Conclusion

The present study found prevalence rates for symptoms of anxiety, depression and emotional distress at 30%, 16% and 26%, respectively. The levels for DA were like those of patients with other ‘dental’ disease, although the prevalence is similar to the UK general population when the borderline scores were considered. OHQoL scores were, however, higher than the non-clinical population but slightly less than those of general (ill-defined) of stomatological or periodontal disease. Older individuals were less likely to experience a frightening feeling (anxiety) or been embarrassed because of problems in the mouth’ (OHQoL) than their younger counterparts. Worse OHQoL scores (OHIP-14) were positively correlated with the number of oral conditions, whereas some depressive symptoms were predicted by the presence of oral symptoms and number of medications.

The present study found significant correlations between the instruments measuring anxiety and depression symptoms, DA and OHQoL with most items of each instrument been significantly correlated with others of different instruments. Although the cause of any relationship between OED and anxiety, depression and OHQoL, is not known, it is evident that this oral mucosal disease can adversely impact upon the psychological well-being of affected persons. However, establishing a causal relationship may, however, be challenging and would need further longitudinal studies.

CHAPTER VI. DEVELOPMENT AND USER-TESTING OF A PATIENT INFORMATION LEAFLET ON ORAL EPITHELIAL DYSPLASIA

6.1. Background

Oral epithelial dysplasia (OED) is a disorder that represents some alterations on the epithelium, which is associated with an increased long-term risk of malignant transformation to oral squamous cell carcinoma (OSCC) (Tilakaratne et al., 2019). With a follow-up period that can take up to 27 years for some lesions linked to OED or its associated oral potentially malignant disorders (OPMDs), there is a need to improve the knowledge and communication with patients about these long-term and potentially cancerous diseases (Jornet et al., 2015, Iocca et al., 2019). If this communication is facilitated by disease-specific information, it can lead to favourable health outcomes of chronic disease by supporting the understanding of the illness nature and its management as well as when and how to seek the professional help if the symptoms recur or become worse (Ley, 1982, Lavery et al., 2007, Hester et al., 2018). Disease-related information is also necessary for effective self-management, which is addressed by the World Health Organisation (WHO) as one of the management strategies for chronic conditions (Epping-Jordan et al., 2004, Lavery et al., 2007).

More specifically, the disease-related tailored information can enhance the information uptake, understanding and recall and to maintain the behavioural changes needed for chronic disease management (Hill, 1997, Kessels, 2003, Lavery et al., 2007). In everyday clinical practice, patients are, however, being commonly overfed with information. A large per cent of this information found to be straightaway forgotten or frequently inaccurate when it is being recalled (Anderson et al., 1979, Kessels, 2003).

The forgotten information may also include those related to the red flags of a disease (Langewitz et al., 2015), which could be a persistent white or red patch or an ulcer in the oral mucosa of patients with OED. Factors such as the patient's existing knowledge, the amount of information given, and age may affect the ability to recall the information (Ley, 1979).

With the older individuals being less likely to recall information than their younger counterparts (McGuire, 1996) and the median age of participants in ODIN-Q study at 65 years old (Chapter 3), patients with OED may encounter some difficulties to remember little disease-related information to remember from their clinical consultations. If they try to search the web, they are unlikely to find trustworthy laypeople-based sources of information related to OED and its commonly associated oral potentially malignant disorders (OPMDs) (Wiriyakijja et al., 2016, Alsoghier et al., 2018, Lorenzo-Pouso et al., 2019). These findings designate the need to present easily understood and read written OED-related information, which can serve as a supplement to the spoken information during consultations to enable patients with different literacy levels to comprehend information and to support their informed and shared decision-making (Hill, 1997, Weiss, 2007, McKinlay et al., 2011).

Of note, 53% of patients in the validation study of the Oral Epithelial Dysplasia Information Needs Questionnaire (ODIN-Q) [Chapter 3] chose printed information materials (e.g. pamphlets, books, magazines, newspapers) which were their second preferred source after one-to-one meeting with health care professionals (HCPs). Patient information leaflets (PILs) is the most frequently used method to present concise and relevant written information for patients that is cost-effective to be produced and reviewed periodically (Lowry, 1995, Kenny et al., 1998). However, PILs are also often limited by their generic-oriented content rather than individually focused and could be useless, discouraging if not professionally prepared (Lowry, 1995). Also, it is often massively produced, instantly outdated, driven by biomedical and political influences and can fail to meet the reader's information needs (IN) (Hall et al., 2008).

An effective PIL is that a patient would notice it and be able to read, comprehend and remember its content (Ley, 1988). It also needs groundwork to be tailored to the patient’s IN and what will make an impact on its purpose (Lowry, 1995, Kenny et al., 1998). Therefore, the present study followed Hill’s model for effective patient education (Hill, 1997), which imply appraising information relevant to patients, develop the content of information accordingly and assess the understanding of this content. Specifically, the present study aims to design a PIL that is based on the IN assessments of 86 patients using ODIN-Q. The initial draft of this PIL will be subsequently appraised by a small group of patients for helpfulness, understanding and satisfaction. Also, health care professionals will have their say on the relevance, clarity and acceptability of this PIL. Once it is ratified, the PIL be assessed in a group of patients with OED who routinely visit the Oral Medicine outpatient Clinics.

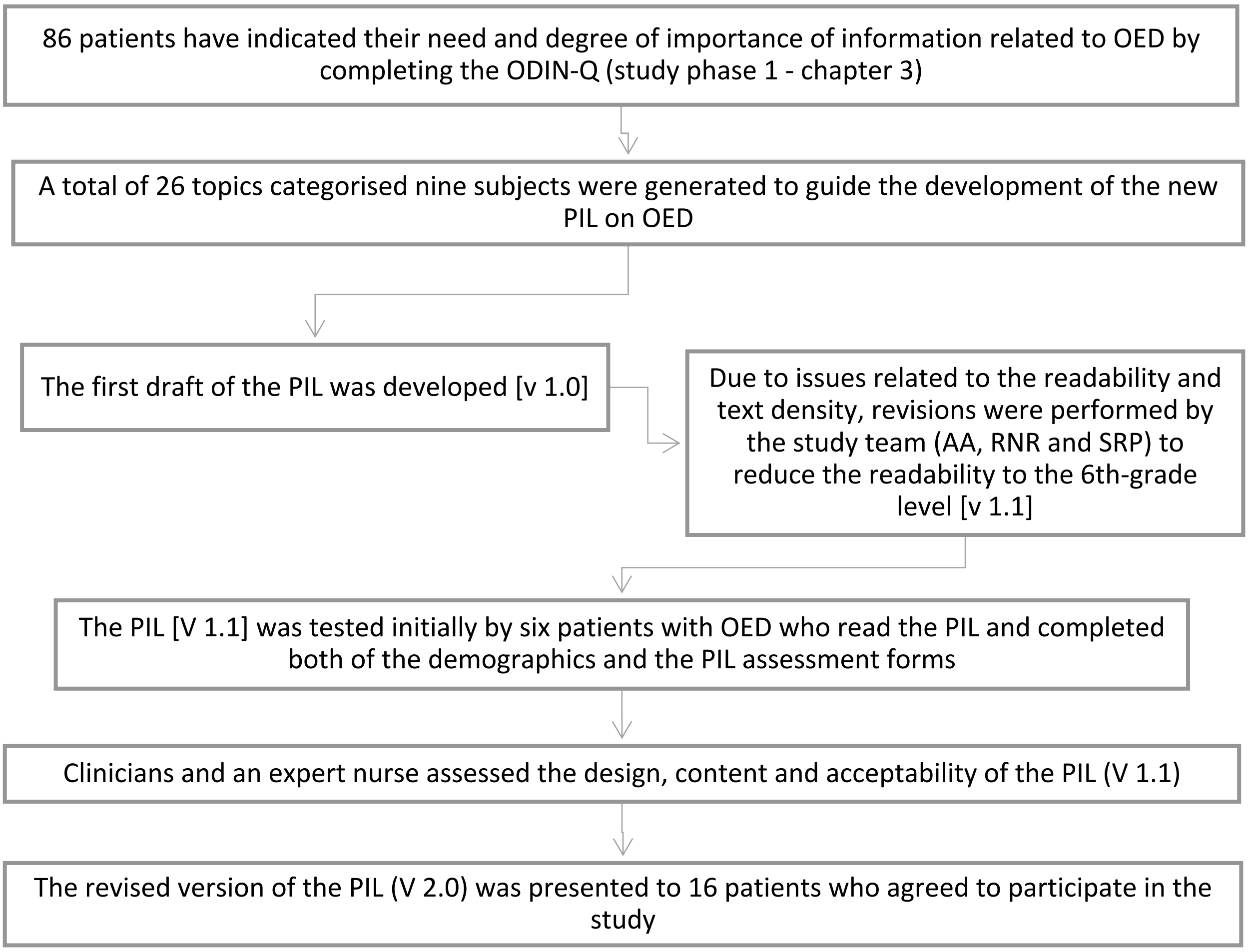
6.2. Methods

This was a prospective and cross-sectional questionnaire-based quantitative study conducted over 9 months (March 2019 to December 2019) at the Oral Medicine and Head and Neck Clinics, UCLH Eastman Dental Hospital and Macmillan Centre, respectively.

6.2.1. Study eligibility criteria

1. Those who were diagnosed with OED as per current standard diagnostic criteria (El-Naggar et al., 2017).
2. Has not participated in phase 1 (development and validation of ODIN-Q).
3. Aged 18 or above at the time of the screening visit, good command of English language both written and spoken.
4. Being able to consent.
5. No concurrent malignancy in the head and neck or elsewhere.

Patients who did not meet these criteria were otherwise excluded. A summary of the steps performed to develop and initially test the new PIL is shown in Figure 6-1.



86 patients have indicated their need and degree of importance of information related to OED by completing the ODIN-Q (study phase 1 - chapter 3)

A total of 26 topics categorised nine subjects were generated to guide the development of the new PIL on OED

The first draft of the PIL was developed [v 1.0]

Due to issues related to the readability and text density, revisions were performed by the study team (AA, RNR and SRP) to reduce the readability to the 6th-grade level [v 1.1]

The PIL [V 1.1] was tested initially by six patients with OED who read the PIL and completed both of the demographics and the PIL assessment forms

Clinicians and an expert nurse assessed the design, content and acceptability of the PIL (V 1.1)

The revised version of the PIL (V 2.0) was presented to 16 patients who agreed to participate in the study

Figure 6-1 Steps performed to develop and assess the new leaflet on OED.

6.2.2. Development of the PIL on OED

To ensure its usefulness before being introduced to patients, the following steps were conducted to the relevance and quality of the new PIL following the guidelines for patient-oriented written health and specifically for PILs (Adepu et al., 2012, Guillot Miss et al., 2016).

Content

Based the patients’ mean and median scores to ODIN-Q degree of importance scale (Chapter 3), a list of 26 topics categorised under nine subjects was generated to guide the content of the new PIL on OED (Table 6-1).

Table 6-1 The list of included subjects (n=9) and topics (n=26) from ODIN-Q phase 1.

What is oral epithelial dysplasia (OED)?
How common is it? What are the risk factors for developing it? Chances of spreading to an adjacent or distant body part? The chance of inheritance. Whether it is contagious or not?
What does oral epithelial dysplasia look like?
Frequency and severity of the symptoms.
What causes oral epithelial dysplasia?
The role of human papilloma virus.
How do we diagnose Oral Epithelial Dysplasia?
What are the benefits, risks, how each test works, and the meaning of test results? The disease grades. Self-management at home.
What are the risks of developing mouth cancer?
How do we treat oral epithelial dysplasia?
Treatment options, benefits, risks, and how each treatment works? What will happen if it is not treated? What is likely to happen to OED in the future? What are the chances of a cure?
How to manage the possible effects of the disease or treatment?
Effects of the disease/treatment on daily physical activities. How the disease/treatment may affect the quality of life? Fear of progression to cancer. How the disease/treatment may affect social life? Seeking another professional opinion.
What can you do?
The lifestyle adjustment (e.g. tobacco and alcohol cessation, and safe sex). Screening and early detection. How to obtain physical support and advice (e.g. who to contact if the warning signs appear)?

What will happen if I continue to smoke or drink alcohol? What is a safe level of alcohol to drink? Diet and nutrition.
How can you help other patients?
Research and recruitment for clinical trials.

ODIN-Q topics excluded due to low importance scores were these related to the community/patient support groups, complementary and alternative medicine, and health promotion. Although some participants presented high importance to how the disease/treatment may affect the job/career, this topic was not included in the PIL as the scores were skewed by 60% of participants who were retired and therefore omitted from the analyses. Moreover, the highly scored topic about the doctor and other health care staff-related experiences could not be included. In turn, this is considered as an integral part of clinical care when HCPs ensure that patients are aware of their professional background, experiences and present role (UK General Medical Council, 2019).

Writing style and presentation

The writing style and presentation of the new leaflet were guided by the following guidelines and tools:

i. UCLH Patients Information Tool (UCLH, 2017), which provides details about the following:
   - Content and presentation of each page of the leaflet [e.g. the front page included the hospital layout, the department name and the title and purpose of the leaflet whereas the back page included the publication and review dates, leaflet code and copyright information].

  - Writing [e.g. focusing on one subject, providing consistent and patient-friendly information, using short sentences and paragraphs] and tone [e.g. active and present tenses].
  - Text and numbers [e.g. left-aligned text, bullet points, Arial with 12pt size font and 1.5 spacing between the lines, avoid abbreviations as well as full capitals, italics and underlining text].
  - Hospital-related information [e.g. sites, services and contact details].

ii. The NHS toolkit for producing patient information (UK Department of Health, 2002b)

  - This toolkit provides general guidance on using relevant and contextual everyday language and a text that is patient-friendly and easy to read and comprehend.
  - Also, it presented useful checklists and templates for written information related to clinical investigations and operations, conditions and its treatments, services and medications.

iii. Information Standard Assessment for Quality of Health Information (NHS England, 2017).

  - This quality standard purposes of supporting organisational production of high-quality health (and care) information related to the public and patients.
  - It is based on six principles; *'information production, evidence sources, user understanding and involvement, end product, feedback and review'*.

iv. Guidelines on writing generic and health information using plain English by Plan English Campaign (http://www.plainenglish.co.uk/).

- *The plain English guide to forms* (Plain English Campaign, 2002): As a part of Plain English Campaign, this form guides presenting consistent information in a logical order using active and personal (you and we) language. Also, to avoid bureaucratic and medical jargon language, which may need longer sentences to explain.
- *How to write medical information in plain English* (Plain English Campaign, 2001): this form presents specific guidance on using plain English in written health care communications such as electronic communication and records, letters and admissions to the hospital and information about non-prescribed medications. It also provides plain explanatory alternatives for commonly used medical jargon such as using '*removing a small amount of tissue for examination in the laboratory'* rather than '*biopsy*', '*a long-lasting disease that changes slowly'* than *'chronic', 'relating to lips'* than *'labial', 'the spreading of tumour cells around the body'* than *'metastasis'* and *'study of the causes of disease; the testing (biopsy) of tissue to check for disease'* than *'pathology'.*

Readability

An online tool (https://readable.com) was used to calculate Flesch-Kincaid Grade Level (FKGL), Flesch Reading Ease Score (FRES) (Flesch, 1948) for this PIL (Kincaid et al., 1975) and issues related to the language, readability, writing style, text density and the reach level to the public. FKGL estimates the number of years of education in the US needed to understand a passage of written material. Whereas FRES provides a score for readability (0 to 100) that is proportional to easy readability. Due to the lack of UK guidelines on the appropriate level of readability for written health information (Fitzsimmons et al., 2010), the appropriate level was considered between 5th- to 6th grade levels bases on the American Academy Association guidelines (Weiss, 2007).

Despite its A grading for readability, the first draft of the PIL [v 1.0] had a readability level at the 8th grade level due to medical jargon (e.g. atypia and dysplasia), 7% of sentences with more than 30 syllables and 46% with more than 20 syllabus, 4.8 characters per word and 13.1 words per paragraph. Subsequently, the PIL [v 1.0] was reviewed by the study team (AA, RNR and SRP) for to resolve these issues and to ensure the accuracy and acceptability of the presented information before its presentation to patients (Robertson et al., 2002, Guillot Miss et al., 2016). Therefore, a revised version with a readability level at the 6th grade was produced [v 1.1].

6.2.3. Study measures

Two assessment questionnaires used to assess the new PIL:

(1) *The satisfaction and Helpfulness with a Patient Information Leaflet Evaluation Form* (Appendix 11); this was adapted from a previous study that assessed the satisfaction of a newly developed PIL for trauma survivors (Robertson et al., 2002).

  - Based on 3- or 4-point rating, the assessment items were about the presentation and layout "*what do you think about the appearance and design of this leaflet?*" [very good, good, poor or very poor], length of the content "*what do you think about the length of its content?*" [too long, about right or too short], quality and volume of the information "*what do you think about quality and* *volume of the information?*" [too much, about right or too little] and whether the content was easy to understand *"how easy the information was to understand"* [very difficult, quite difficult, quite easy or very easy].

- Further irrelevant trauma-related questions used in Roberson's study were not considered.

(2) *The UCLH Patient Information Feedback Form* (Appendix 12); this 6-item form rated by 5-point scale (5 = excellent, 1 = poor) was used as part of the UCLH Trust's approval process.

- Unlike the former form, the how easy and understandable a text was presented in two questions; *"easy to understand?"* and *"was the text easy to read?".*
- Other included items questioned the helpfulness of the text "*helpful?"* or images "*would images be helpful?*", understanding of the topic "*do you have a good understanding of the subject?"* and colours used "*did you like the colours used?*".
- Also, two open-ended questions were included; *'were there any things you found difficult to understand in this leaflet or was there anything you felt was not covered?'* (Q7) and *'do you have any other suggestions about how we could improve this leaflet?'* (Q8).

Furthermore, the socio-demographic questionnaire was presented along with these forms to obtain information about age, gender, ethnicity, educational level, employment status, and smoking/alcohol intake (Appendix 8). Clinical data were extracted from the participants' paper and electronic medical records using a specific form (Appendix 4).

6.2.4. Data analysis and representation

The quantitative and qualitative data, including the respondents' demographics, responses to the assessment forms and clinical variables, was transferred to a Microsoft Excel (version 16.32) proforma as numerical variables. The descriptive statistics in numbers (mean, median and standard deviation) and percentages were conducted using IBM SPSS software (version 22.0).

6.2.5. Ethical consideration

As part of ODIN-Q study (Chapters 3 and 5), the study was initially registered with the UCLH/UCL Joint Research Office [JRO reference number: 18/0203, IRAS project ID: 242552] and received the ethical approval from the NHS Health Research Authority, Research Ethics Committees [London – City & East Research Ethics Committee, reference, 18/LO/1340] (Appendix 5). The eligible patients were introduced to the study after their routine care appointment at Oral Medicine clinics of the UCLH Eastman Dental Hospital. Those who agreed were asked to read the Participant Information Sheet and sign the Informed Consent Form (Appendix 6). Furthermore, the revised version of the PIL was submitted to the UCLH for approvals to use their PIL templates and information and to be routinely used after assessments. The local clinical governance group at UCLH gave their permission with no further changes needed.

6.2.6. Initial assessments of the PIL content by patients and health care professionals

Five males and one female with a mean age of 69 years old have agreed to participate in the initial assessment of the PIL on OED. All six participants were of White ethnicity; three had a bachelor's degree or higher, four were retired, one currently smoking e-cigarette and three were presently drinking alcohol. Regarding their clinical characteristics, four had a diagnosis of at least one of the OPMDs, mainly the oral lichen planus/lichenoid reaction (n=3). The average number of OED lesions was 1.8 per participant and a total number of 11 lesions (mild = 10, mild to moderate = 1). Buccal mucosa was the most affected site (Table 6-2).

Table 6-2 Participants' characteristics in the initial assessment of the PIL on OED (n=6)

ID	**Demographics**								**Clinical features of OED**		
	Gen	*Age*	*Ethnicity*	*Education*	*Employment*	*Smoking*	*Alcohol (units per day)**	*Date of the first diagnosis*	*Oral condition*	*No. of OED lesions*	*Site (degree)*
301	M	55	White-British	Bachelor's degree	Employed full-time	E-cigarette	5 to 6 units/d	Feb 2015	None	1	ManG (mild)
302	M	77	White - British	Postgraduate degree	Retired	Never	5 to 6 units/d	Aug 2011	VL	2	HP (mild), BM (mild)
303	M	84	White - any other	*Missing*	Retired	*Missing*	*Missing*	Jan 2014	OLP/LR	1	ManG (mild)
304	M	76	White - British	High school diploma	Retired	Never	Never	Mar 2015	GvHD/Imm.Sup	1	BM (mild)
305	M	65	White - British	High school diploma	Retired	Never	Past	Jul 2011	OLP/LR	5	BM (mild, mild, mild), LT (mild, mild to moderate)
306	F	59	White - any other	Bachelor's degree	Employed full-time	Never	Occasional	Jul 2014	OLP/LR	1	MaxG (mild)

*In a typical day.

1. Gen, Gender; **M**, male; **F**, female

2. Oral condition/disease: **GvHD**, Graft versus host disease; **Imm.sup**, immunosuppression; **LR**, lichenoid reaction; **OL**, oral leukoplakia; **OLP**, oral lichen planus; **VL**; verrucous leukoplakia.

3. Sites of dysplasia: **BM**, buccal mucosa; **HP**, hard palate; **LT**, lateral tongue; **ManG**: mandibular gingiva; **MaxG**, maxillary gingiva.

Regarding the assessments of the PIL, most participants thought the initial draft was very good in appearance and design (n=4), about right with the length (n=3) and quality and volume (4) and very easy to understand (n=3). However, three participants thought it was too long of length or too much of amount (Figure 6-2). Therefore, this indicated the need to shorten and reduce the length and amount, respectively. One participant (study ID, 308) did not complete the satisfaction and helpfulness form.

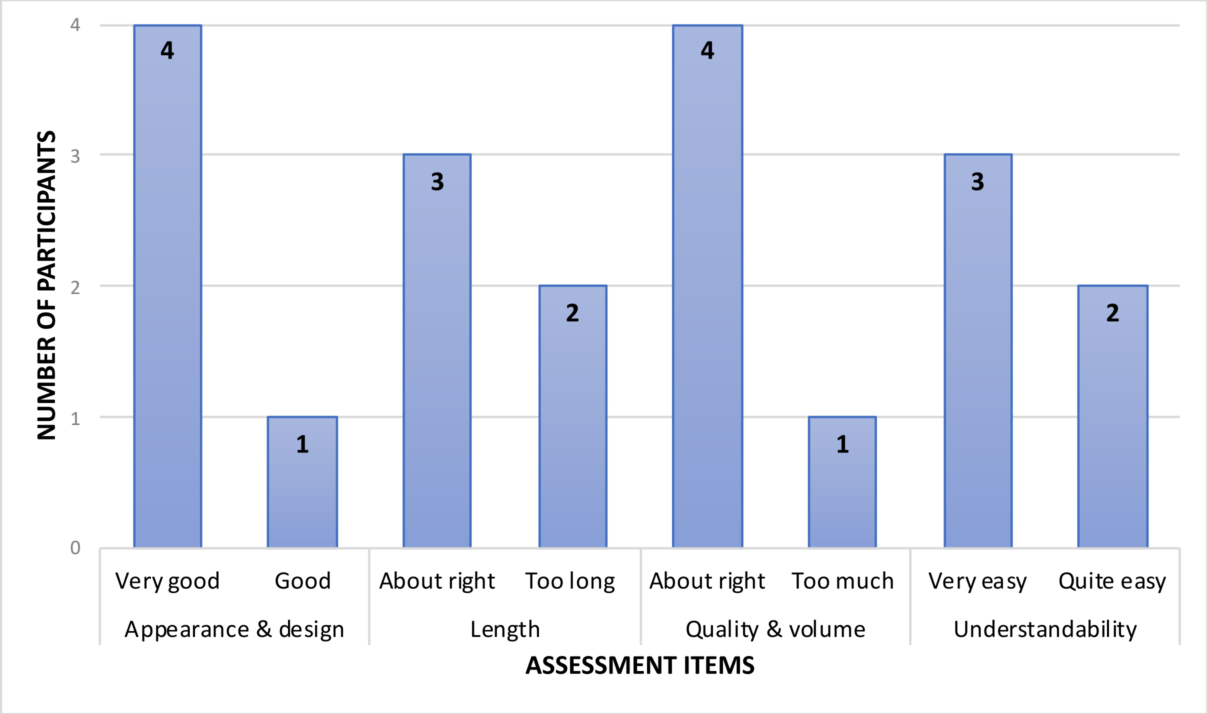


Figure 6-2 The assessments of helpfulness and satisfaction with the PIL [V 1.1] (n=13).

Similarly, the highest scores to the UCLH assessment form were given to its understandability (mean score = 4.33), helpfulness (4.16), readability (4) and having a good understanding of the subject (4). Relatively low scores were however given to the images and colours used (3.66 for each). One of the participants (study ID, 304) did not complete question 5 (Figure 6-3).

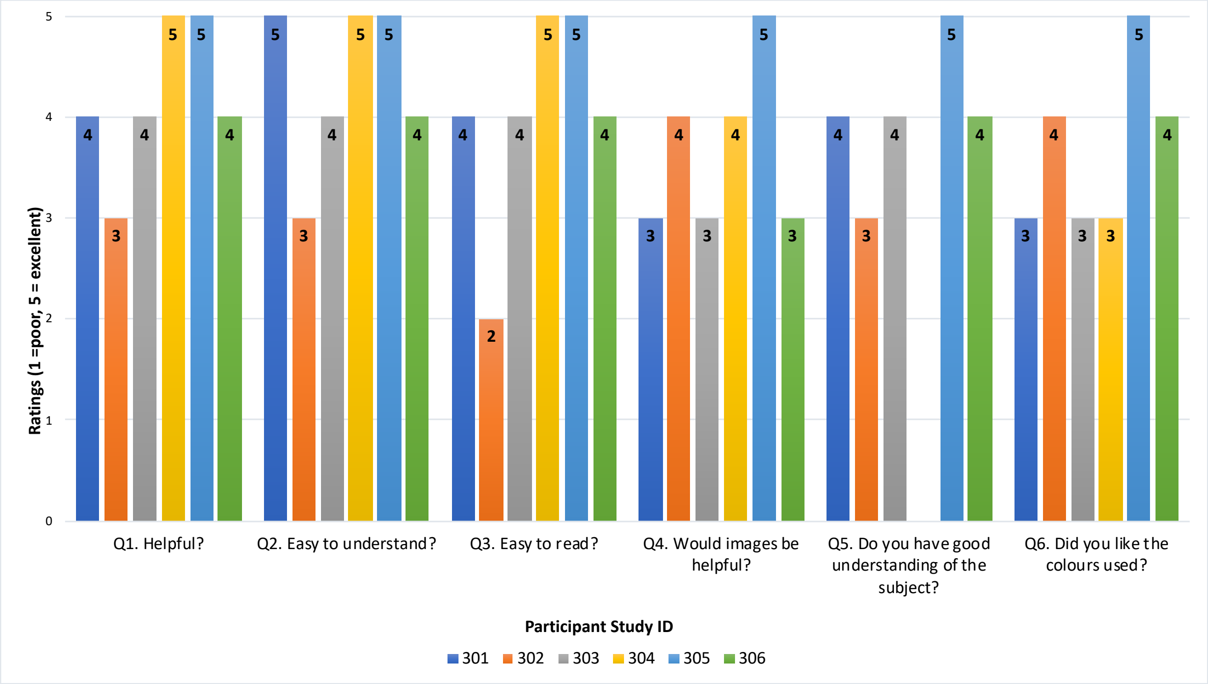


Figure 6-3 Responses to the UCLH assessments for the PIL on OED [V 1.1] (n=6).

Furthermore, a thorough feedback was received from the participants on the open-ended assessment questions as toward the content, design, format and layout of the initial draft of the PIL. The list of actions performed for each comment/s is shown in Table 6-3. Also, the implemented actions or explanations based on the reviews of clinicians and nurses on the content, layout, details of the NHS services are shown in Table 6-4.

Table 6-3 Comments from patients and the performed actions on the PIL [v 1.1].

Question	Comment/s	Action/s taken
Q7. Were there any things you found difficult to understand in this leaflet or was there anything you felt was not covered?'	*Not sure that figure 1 is adding much -> more useful to have comparison picture of healthy vs. mild vs severe .. or cartoon/illustration* (study ID, 301).	Half of the participants found the presented images useful. Thus, the study team decided to retain them for version 2.0 to see what other respondents would view it.
	The purpose of figure 1 is unclear. It should be integrated into the text (303).	
	After the Photos at Figure 1 on page 1, could I suggest you insert some photos showing dysplasia so patients can see what an abnormal mouth looks like (305).	
	A large print version of this leaflet should be avoidable (303).	The A 4-page format and 12-point font size were maintained to accommodate the important and needed information indicated by patients (Chapter 3) and in line with the NHS toolkit (UK Department of Health, 2002b).
	Add smoking cannabis as this is rife in this country, I am sad to say, among both young persons, middle aged and some older people (305).	There is no evidence available to support the correlation between cannabis and OED. One study refuted the effect/correlation with cervical dysplasia (D'Souza et al., 2010).
	I suggest the first 3 bullet points are re-written so they flow more logically and include the inside of the cheek as an area where dysplasia can occur too (305).	The changes were performed as suggested.
	Change "raise the chance" to "increase the chance" (305).	

	Change “might lead” to “may lead” (305).	The changes were performed as suggested.
	Add “Tobacco Chewing” as a number of ethnic groups chew tobacco (305).	
	Add “any further” to “This is to look for changes in the lining of your mouth” (305).	
	when it says “if your diagnosis is affecting your mental health” I feel this is too 'medical!! Prefer if you feel anxious or if your diagnosis is affecting how you feel/your mood etc (306).	The change was performed as suggested; ‘your mental health’ was changed to ‘how you feel’
Q8. Do you have any other suggestions about how we could improve this leaflet?’	*Overall very good but think the paragraph + the spacing could be improved .. currently all bullets have a tendency to run into one another* (301)	The changes and shortening of the content and volume were performed as suggested.
	Highly unnecessarily long, however, I understand it. Thank you (302).	
	Better a paper printed fold out not stippled	Version 2 of this PIL was presented as an A foldable A4 format.

Table 6-4 Comments from clinicians and nurses and the performed actions [v 1.1].

Clinical staff	**Feedback**	**Action/s taken**
Senior nurse 1	*Change “The is to identify any changes of your mouth lining.” (page 3) to “This is to identify any changes of your mouth lining.”*	The changes were performed as suggested.
	Change “Treatment usually require surgical removal..” to “Treatment usually requires surgical removal”	
	Reduce the margins	
	Reword ‘We may not remove the areas with mild but examining you periodically’	The word ‘dysplasia’ was added
Clinician 1	*To remove the websites for NHS services for smoking and alcohol advice and keep the names only.*	The change was performed as suggested; this might be useful as the address of the NHS services may change.
Clinician 2	*These sentences may contradict each other:* *- We want all dysplasia to be removed whenever possible.* *- We may not remove the areas with mild but examining you periodically.*	Not necessarily true. The first sentence is in line with next two related to the lesion with mild dysplasia, ‘*We may not remove the areas with mild but examining you periodically.*’ and those of moderate and severe dysplasia, ‘*Most moderate dysplasia and all severe dysplasia needs removal’*.

Therefore, the final version of the PIL (v 2.0) was produced by the study team (AA, RNR and SRP) after reviewing the feedback from patients and health care professionals to the initial draft (Appendix 13). Although the initial version was developed and printed using Microsoft Word (v 16.17), the revised version was edited by the hospital’s patient experience team using sophisticated graphic software for digital media (Adobe InDesign) (Culliford et al., 2019). This version was printed as A4-double sided and foldable format on Matte papers using laser coloured printer (*printing setup: A3 portrait-oriented booklet [both sides] with left binding*). Using an online readability tool (https://readable.com), this version was at the 6th grade level [Flesch-Kincaid Grade Level (Kincaid et al., 1975)] which is in line with guidelines for written health information (Weiss, 2007).

Also, the 26-item Patient Education Materials Assessment Tool for Printable Materials (PEMAT-P) (Shoemaker et al., 2014) was used to ensure the that individuals from different educational levels would be able to understand (19 items) and subsequently be able to know what to do with the information presented in the leaflet (7 items) (Lipari et al., 2019). Based on a binary scale (yes = 1, no = 0 or not applicable), the total percentage for each measure is calculated using a determined formula [(the total sum score/the number of items) × (100)]. The understandability and actionability rates were at 100% (18 out of 18 points) and 80%. (5 out of 6 points), respectively (Table 6-5).

Table 6-5 PEMAT-P scores of the PIL (v 2.0).

No	Item	Rating
	UNDERSTANDABILITY	
1	'The material makes its purpose completely evident.'	1
2	'The material does not include information or content that distracts from its purpose.'	1
3	'The material uses common, everyday language.'	1
4	'Medical terms are used only to familiarize audience with the terms. When used, medical terms are defined.'	1
5	'The material uses the active voice.'	1
6	'Numbers appearing in the material are clear and easy to understand.'	1
7	'The material does not expect the user to perform calculations.'	1
8	'The material breaks or "chunks" information into short sections.'	1
9	'The material's sections have informative headers.'	1
10	'The material presents information in a logical sequence.'	1
11	'The material provides a summary.'	1

12	‘The material uses visual cues (e.g., arrows, boxes, bullets, bold, larger font, highlighting) to draw attention to key points.’	1
15	‘The material uses visual aids whenever they could make content more easily understood (e.g., illustration of healthy portion size).’	1
16	‘The material’s visual aids reinforce rather than distract from the content.’	1
17	‘The material’s visual aids have clear titles or captions.’	1
18	‘The material uses illustrations and photographs that are clear and uncluttered.’	1
19	‘The material uses simple tables with short and clear row and column headings.’	NA
	ACTIONABILITY	
20	‘The material clearly identifies at least one action the user can take.’	1
21	‘The material addresses the user directly when describing actions.’	1
22	‘The material breaks down any action into manageable, explicit steps.’	1
23	‘The material provides a tangible tool (e.g., menu planners, checklists) whenever it could help the user take action.’	0
24	‘The material provides simple instructions or examples of how to perform calculations.’	NA
25	‘The material explains how to use the charts, graphs, tables, or diagrams to take actions.’	1
26	‘The material uses visual aids whenever they could make it easier to act on the instructions.’	1

6.3. Results

Twenty patients, who met all inclusion criteria, were initially invited to participate during the study recruitment period between September to December 2019. Three were excluded due to the inability to read or communicate using the English language and one due to clinical judgement (memory issues). The remaining sixteen participants have agreed to participate and signed the informed consent forms.

Sample characteristics

Due to multiple missing data on all questionnaires, the responses from two participants were excluded from the analyses. Another participant did not complete the satisfaction and helpfulness assessment form, but did the other forms and therefore, was included. Hence, the responses from 14 participants were included in the descriptive analyses. Those participants were eleven males and three females with a mean and median age of 64 (±15) and 69, respectively [highest = 81, lowest = 25].

Respondents were either Asians (n=9) or White (n=5) with educational background of less than high school (n=4), high school diploma (n=1), some college or bachelor's degree (n=5), postgraduate degree (n=3) and others (n=1). Nine of the 14 participants were retired whereas five were either part-time or full-time employed. Regarding tobacco use, seven have never been users, seven were past smokers (n=4) or chewers tobacco (n=3), and none were current users. Regarding alcohol drinking, three have never drinkers, five were past drinkers, and five were occasional or regular drinkers.

By reviewing the paper and clinical medical records of the respondents, thirteen of the 14 participants had at least one or more pre-existing or associated oral potential malignant disorder (OPMD) including the oral lichen planus (OLP) /lichenoid reaction (LR) (n=5), oral submucous fibrosis (n=5), oral leukoplakia and its verrucous form (n=3) and actinic cheilitis (n=1). Three respondents presented a history of oral squamous cell carcinoma (OSCC). Despite the lack of evidence on the relationship with OED, one participant had the diagnosis of Sjogren’s syndrome, which was possibly related to the pulmonary sarcoidosis.

Regarding OED characteristics, five respondents received the first diagnosis of OED within the last five years, three since 5 to 10 years and five of 10 years or more. Moreover, the 14 respondents presented with a total number of 33 OED lesions in 10 different sites of the oral cavity. The mean and median numbers of OED lesions were at 2.35 and 2 lesions per participant, respectively [highest = 6, lowest = 1]. These lesions were graded by histopathology as mild (n=17), mild to moderate (n=7), moderate (n=3), moderate to severe (n=2) and severe OED (n=4). Both of the tongue [dorsum, lateral and ventral sides] and the buccal mucosa were considered the most affected sites by these lesions (Table 6-6).

Table 6-6 The demographic and clinical characteristics for participants (n=14).

ID	**Demographics**								**Clinical features of OED**		
	Gen	*Age*	*Ethnicity*	*Education*	*Employment*	*Tobacco use*	*Alcohol (units per day)*	*Associated oral condition*	*Date of the first diagnosis*	*No. of OED lesions*	*Site (degree)*
307	M	69	Asian or Asian British - Indian	High school diploma	Retired	Never	Current (occasional)	VL, OSF, OSCC	Sep 2007	6	LL (moderate, mild), BM (mild to moderate, OSCC), ManG (severe, OSCC), RA (severe), HP (mild).
308	M	49	Asian or Asian British - Any Other	Less than high school	Part-time	Never	Never	OSF, OL	Nov 2018	2	BM (mild to moderate, mild)
309	M	81	Asian or Asian British - Pakistan	Bachelor's degree	Retired	Past (chewed)	Past	OSF	Sep 2008	1	BM (mild)
310	F	79	White - Any Other	Some college	Retired	Past (smoked)	Past	OLP/LR	Mar 2007	1	LT (mild)
311	M	76	Asian or Asian British - Indian	Less than high school	Retired	Past (chewed)	Current (3-4 u/d)	OSF	Oct 2010	1	DT (mild)
312	M	59	Asian - British	Postgraduate degree	Full-time	Never	Current (1-2 u/d)	OL	Jan 2018	2	LT (mild, mild to moderate)
313	F	74	Asian or Asian British - Any other	Bachelor's degree	Retired	Never	Never	Sarc/SS	Oct 2018	1	VT (mild)

314	M	51	Asian or Asian British - Any other	Postgraduate degree	Self-employed	Past (chewed)	Past	OSF, OSCC	Dec 2013	3	BM (OSCC, 3X mild)
316	M	57	White - British	Bachelor's degree	Self-employed	Never	Current (1-2 u/d)	OLP/LR	Aug 2008	4	LT (moderate to severe, moderate OSCC), VT (mild, moderate to severe)
317	M	72	White - Any other	Some college	Retired	Past (smoked)	Missing	OLP/LR	1993	1	FOM (mild)
318	F	69	Asian Or Asian British - Any other	Postgraduate degree	Retired	Never	Current (occasional)	OLP/LR	Jul 2009	1	MaxG (mild)
319	M	68	White - British	Less than high school	Retired	Past (smoked)	Past	OLP/LR, OSCC	Feb 2014	6	BM (2X mild to moderate, 3X mild, OSCC), HP (severe)
320	M	25	Asian or Asian British - Any other	Others	Retired	Never	Never	None	May 2016	2	LT (2X mild to moderate)
322	M	72	White-British	Less than high school	Full-time	Past (smoked)	Past	AC	Oct 2017	2	LL (severe, moderate)

**In a typical day.*

*1. Gen, Gender; **M**, male; **F**, female*

*2. Oral condition/disease: **AC**, actinic cheilitis; **LR**, lichenoid reaction; **OSCC**; oral squamous cell carcinoma; **OL**, oral leukoplakia; **OLP**, oral lichen planus; **Sarc**, sarcoidosis; **SS**, Sjogren’s syndrome **VL**; verrucous leukoplakia*

*3. Sites of dysplasia: **BM,** buccal mucosa; **DT**, dorsum of the tongue; **FOM**, floor of the mouth; **HP**, hard palate; **LT**, lateral tongue; **LL**, lower lip; **ManG**, mandibular gingiva; **MaxG**, maxillary gingiva; **RA**, retromolar area; **VT**, ventral tongue*

The assessments of the patient information leaflet on oral epithelial dysplasia

The assessment of satisfaction and helpfulness of the PIL showed that 11 (84%) out of the 13 participants viewed the appearance and design as good or very good. In contrast, two participants considered it as poor or very poor. Moreover, 12 (92%) and 13 (100%) of them thought of the length as well as the quality and volume are about right, respectively. Only one participant, who was of Asian ethnicity, found the present information very difficult to understand and notably preferred to receive the presented information as audio. In contrast, all the remaining participants found it quite or very easy to understand (Figure 6-4).

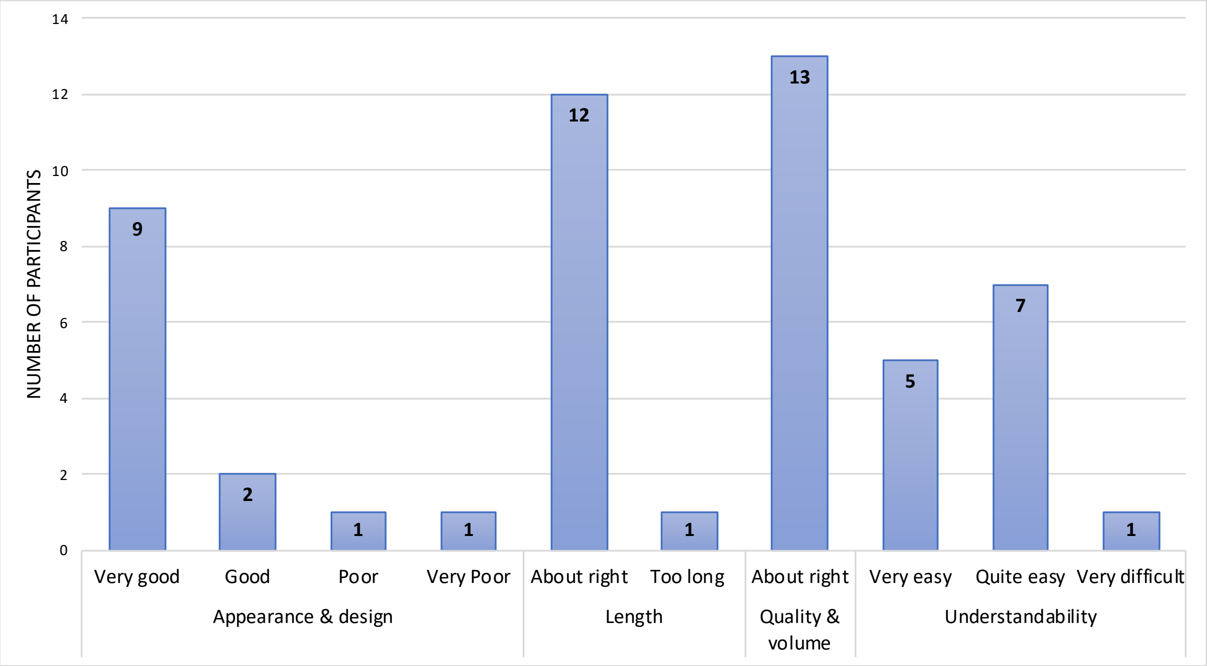


Figure 6-4 The satisfaction and helpfulness of the PIL [v 2.0] (n=13).

The analyses of the UCLH assessment form showed all mean and median scores were of 4 or higher (1 = poor, 5 = excellent). Questions related to the helpfulness (Q1) and colours used (Q6) obtained the highest median scores of 5 followed by those related to readability (Q3), images being helpful (Q4) and having a good understanding of the subject (Q5) (Figure 6-6).

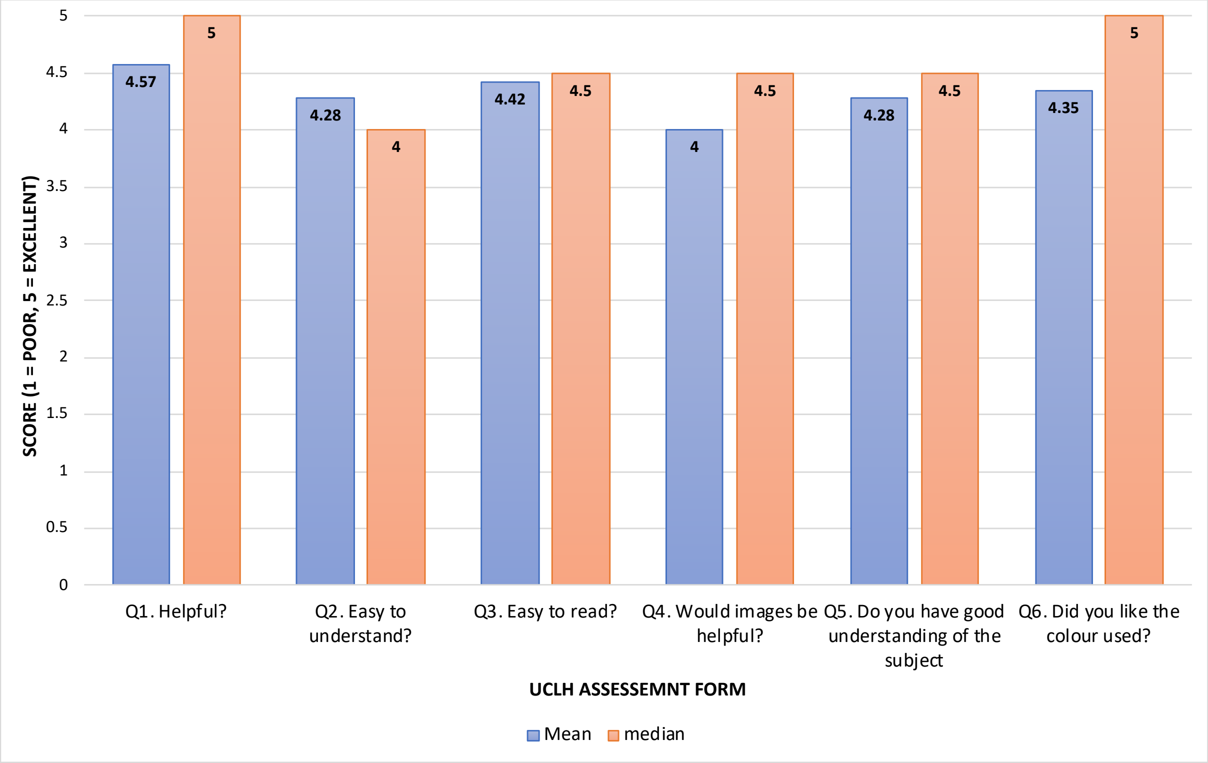


Figure 6-5 Responses to the UCLH assessment form on the PIL [v 2.0] (n=14).

Based on 1-5 scale (1 = poor, 5 = excellent), the majority of individual presented high scores (≥ 4) to content being easy to read (93%), helpful (92%), easy to understand (85%), support a good understanding of the subject (86%) and liked the colours used (86%). Although 64% of respondents viewed images as helpful, the remaining 36% considered these as neutrally helping or not helpful (Table 6-7). Furthermore, the participants provided useful feedback to the open-ended questions (ULCH assessment form) which questioned whether any things were difficult by remarking that ***'nothing difficult to understand'*** (study ID, 312), ***'very good'*** (317), and ***'the subject matter was completed in an easy to read user friendly representation'*** (322).

Suggestions to improve the leaflet included ***'perhaps also considering an effective essay'*** (312***), 'it is better to make this leaflet shorter'*** (313), and ***'photographs of typical dysplasia and lichen planus could be useful'*** (319). On the preference for the format of the leaflet, one participant (309) preferred an audio version of the leaflet, and three participants preferred an Easy Read format (313, 316 and 317).

Table 6-7 The participants' responses to the PIL assessment forms (n=14).

Study ID	**UCLH assessment form**				**Satisfaction and helpfulness with the PIL (1 = poor, 5 = excellent)**					
	Appearance & design	*Length*	*Quality & volume*	*Understandability*	*Helpful*	*Easy to understand*	*Easy to read*	*Images be helpful*	*Good understanding*	*Colours used*
307	Very good	About right	About right	Very easy	5	5	5	5	5	5
308	Good	About right	About right	Very difficult	4	3	5	3	4	3
309	Very good	About right	About right	Quite easy	3	3	4	2	2	4
310	Very good	About right	About right	Quite easy	5	5	5	5	5	5
311	Very good	About right	About right	Very easy	5	5	5	5	5	5
312	Very good	About right	About right	Quite easy	5	4	4	5	3	5
313	Very good	Too long	About right	Very easy	5	4	4	5	5	4
314	Poor	About right	About right	Quite easy	5	4	4	3	5	5
316	Very poor	About right	About right	Quite easy	4	4	4	2	4	2
317	Very good	About right	About right	Very easy	4	4	3	4	4	4
318	Very good	About right	About right	Very easy	5	5	5	5	5	5
319	Very good	About right	About right	Quite easy	5	5	5	3	4	5
320	Good	About right	About right	Quite easy	5	5	5	5	5	5
322	Good	About right	About right	Quite easy	4	4	4	4	4	4

The responses to the assessment forms and open-ended questions were discussed in a panel of oral medicine experts, and a decision was made to maintain the revised version (v 2.0) dated September 2019 (Appendix 13) without changes. The leaflet will be reviewed in 18 months to see whether further changes needed.

6.4. Discussion

Primary and secondary preventions of oral malignancies aim at reducing identifiable risk behaviours (i.e. tobacco use, alcohol consumption and betel nut) and early detection of OPMDs, respectively (Thomson, 2015). This indicates the need to promote the individual's healthier behaviour changes and knowledge about the disease (i.e. OED) and recognition of worrisome symptoms, to maintain these preventions. With the present evidence supporting the link between these risky behaviours to the development of OED or its malignant transformation OED (Jaber et al., 1999, Ho et al., 2012, Porter et al., 2018), tailored health information can be a useful educational tool to adopt healthier lifestyle behaviours and reduce the risky ones (Robertson, 2008). Despite the present lack of well-established evidence on its link to OED, the behaviour changes may also include the risky sexual behaviours linked to high-risk oral HPV infections (McCord et al., 2013, Lerman et al., 2017, Osazuwa-Peters et al., 2019).

Health belief model suggests that behavioural changes are determined by the individual’s weighting of the benefits of change and the cost of consequences of risky behaviours (Becker, 1974, Rosenstock, 1974, Rosenstock, 2005). Common triggers for behavioural change include the internal cues (e.g. experiencing worrying symptoms) and external ones (e.g. receiving health information from public health campaigns or leaflets) (Wacker, 1990, Robertson, 2008). Hence, providing tailored information to those with OED can support their self-efficacy to develop skills and motivation necessary for the positive behavioural changes (Bandura, 1977, Bandura, 1994, Hester et al., 2018).

The new needs-based and importance-based PIL on OED was developed following the guidelines and standards for written health information to patients and specifically for PILs (UK Department of Health, 2002b, NHS England, 2017). It has passed through several assessments by patients and HCPs to ensure its adequacy as a source of information about OED for patients who visit the Oral Medicine Clinics. These assessments were in line with a leaflet quality checklist, which recommends personalising its evidence-based and needs-based content to the targeted group, to analytically test it by a minimum of two patients and two clinicians from the same speciality and to assess its readability using a standardised test (Sustersic et al., 2017).

First, it was developed based on the input of 111 patients with OED: 5 patients who help to establish the content validity of the new OED-specific IN instrument (ODIN-Q), 86 who addresses the unmet IN and the degree of importance for each topic and domains using ODIN-Q, six who initially assessed the new PIL and 14 who assessed the revised version of this leaflet. A teamwork of clinicians is highly essential to ensure the consistency and scientific rigour of patient-oriented written information (Lowry, 1995, Kenny et al., 1998). Thus, 19 HCPs were vitally involved in the development of ODIN-Q that led to the present leaflet and the leaflet itself. Of which, two expert clinicians helped to generate the content of ODIN-Q, 12 helped to assess its content validity, two revised the content and readability of the new PIL and three HCPs, who were senior and junior clinicians and a senior nurse, helped to generate a revised version of the PIL. Finally, the initial PIL was tested for readability using a commonly used formula (FKGL), and the result was challenging - it was at the 8th grade level. Replacing medical jargon (e.g. atypia, epithelial and pathologist) to those familiar to the layperson, reducing long words and sentences with many syllabuses and using gender- and group- balanced and individualistic by using 'you' and 'we' (Lowry, 1995) have led to a readability level of 6th grade level. Moreover, the revised PIL demonstrated its usability to patients by obtaining high percentages for its content to be understood (100%), but slightly less for potential actions upon its key messages (80%) using a highly used and validated instrument (PEMAT-P) (Shoemaker et al., 2014, Mastroianni et al., 2019). These rates were higher than other patient educational materials on alcohol abuse (84% and 50%) (Sharma et al., 2018) but comparable to those of rare disease (94% and 90) (Badiu et al., 2017) and sepsis (80% and 90%) (Schorr et al., 2018).

Most respondents accepted the revised version with no necessary changes needed. All respondents in the present study except one indicated a good understanding of the topic. Still, the evidence cannot be verified as the questions do not specify if the content led to this good understanding or it was a result of pre-existing knowledge. Questions on whether the new leaflet led to short- or long-term impact on the knowledge and motivation for follow-up screening were not addressed presently. Boundouki and colleagues addressed that a leaflet on oral cancer has improved understanding and acceptance for screening 2-month period among patients who received the leaflet compared to the non-leaflet group (Boundouki et al., 2004). The previous study also noted that the knowledge levels among individuals who had the leaflet were conversely reduced with the time whereas individuals of older age, lower knowledge at the baseline and who currently smoke were highly likely to re-read the leaflet. However, the study authors questioned whether the information could lead to favourable behavioural change to prevent oral cancer.

While the leaflet indicates who to contact if the worrisome symptoms arise, it also encourages patients to ask questions and seek professional help from the dentist, doctor or specialist about the possible physical and psychological aspects related to OED or is treatment (Lowry, 1995). To avoid lengthy content, readers were encouraged to ask for the previously developed PIL about the oral mucosal biopsy - if they wish to know more. This leaflet provides detailed information on what a mucosal biopsy is, why it is needed, procedures, post-operative care, and who to contact if help is required. Likewise, the links to sources of patient-based information about OED and OPMDs were indicated; the British and Irish Society of Oral Medicine (https://www.bisom.org.uk) and the British Association of Dermatologists (http://www.bad.org.uk).

Possibly sensitive topics to some individuals such as those related to the malignant transformation as well as the sexual transmission of HPV and unsafe sex were carefully and unambiguously addressed (Lowry, 1995). Although inducing fear was found to elicit behavioural changes related to smoking compared to positive messages (Montazeri et al., 1997), the present PIL has only included short and balanced messages; one on the link of both habits to dysplasia and another about talking to the GP for advice and two web-based NHS services. The first service, Smoke Free (https://www.nhs.uk/smokefree), provides personal individual plan based three questions; how soon the first cigarette to be smoked after waking up (e.g. less than 5 minutes, between 6 to 30 minutes or more than 30 minutes), how many cigarettes smoked per day and what methods previously tried to quit smoking (e.g. professional advice by the GP or pharmacist, tobacco or not tobacco-based nicotine replacement therapies and e-cigarettes/vapes). The service also offers free professional support to quit smoking, frequently asked questions about quitting, benefits of quitting on own health, family and money and videos of personal success stories for quitting. Using such services can possibly increase the chances of smoking cessation, especially when combinedly implemented [e.g. telephone counselling, education and/or clinical interventions] (Naidoo et al., 2004).

The other service, Alcohol Support (https://www.nhs.uk/live-well/alcohol-support/), presented some facts about alcohol (e.g. units, calories, risks, binge and social drinking) in addition to advice and support (e.g. where to find help, tips to cut down drinking and hangover and caring of an alcoholic person). It also provides the details of supportive UK contacts such as the national alcohol helpline [0300 123 1110], the National Association for Children of Alcoholics [0800 358 3456] as well as community support agencies and charities including Alcoholic Anonymous (https://www.alcoholics-anonymous.org.uk), AddAction (https://www.addaction.org.uk) Adfam (https://www.addaction.org.uk) and UK SMART Recovery (https://smartrecovery.org.uk).

A properly designed and engaging information for a leaflet is proportionately crucial to its content to induce an impact (Robertson, 2008). Illustrations such as diagrams and images can be powerful tools to increase the individual's attention and promote the information understanding, retention and recall (Lowry, 1995, Messaris, 1997, Houts et al., 2006). A systematic review by McWhirter and Hoffman-Goetz noted greater accuracy of skin self-examination and melanoma detection especially among high-risk patients after images of the benign and malignant skin lesions were used (McWhirter et al., 2013). The previous study indicated a temporary visual memory of these lesions, and therefore images need to be re-introduced simultaneously with self-examination techniques. However, most of the reviewed studies presented the images of actual lesions of participants or generic benign and cancerous lesions, rather than the healthy ones as in the present study.

Of note, three of the respondents in the present study suggested adding images of different grades of dysplasia (301), those of typical dysplasia (305 and 319) and oral lichen planus (319). The reason these were however avoided was to avoid intense fear-appealing messages (Rubenking et al., 2014, Rhodes, 2015) specifically among those with salient oral lesions, lower OED grades and those presented no OPMDs. These messages can be useful for positive attitudes toward dental health (Baron et al., 1994) and performing breast self-examination (Ruiter et al., 2001). However, the outcomes of using such a message are often unpredictable, thus, should be carefully utilised (Weinman, 1990). Alternatively, images of normal-looking oral mucosa were presented as a reference for self-monitoring, to notice suspicious changes on the oral mucosa and to seek professional help accordingly (Oliveria et al., 2004, Chiu et al., 2006). As studies also support its benefits to empower individuals with low literacy (Smith et al., 2008, van Beusekom et al., 2016), two of four respondents in the present study, who had less than high school education (311 and 322), indicated the helpfulness of the presented images. Whereas the other two (308 and 319) noted neutral helpfulness (3 out of 5).

Different PILs formats and printing must be offered base on their preference and abilities (Marsay, 2017). For instance, three respondents preferred an Easy Read format of the leaflet despite its current low readability level at 6th grade. Aside from using straightforward and commonly used words and phrases, illustrations such as images, diagrams and symbols are essential to make an easy read leaflet (Marsay, 2017, Read Easy UK, 2020). Fourteen basic rules were suggested by the UK Department of Health for best practice when writing information as Easy Read including those related to using both of words and pictures for each idea, using pictures and words that is easy to see and interpret and short words, sentences and document (Department of Health, 2009). Offering this format is necessary, especially with persons with low readability skills or learning disabilities (Marsay, 2017). Health care institutes may also consider offering a communication professional advocate and communication aids which include letters, words, symbols and electronic-based systems to support communication with these individuals (Mencap, 2010).

Moreover, a participant in the present study who had some visual impairment and the English was not his first language preferred a recorded audio format of the leaflet (309). Notably, 28% of 219 individuals who had complete or some visual loss in the UK preferred to receive information as audio, 25% of them opted for large print and 15% for both formats (Thurston et al., 2010). Nevertheless, most of those individuals were not offered their preferred formats for information, which may have left some individuals with unmet IN. Furthermore, some individuals may prefer to receive information using Braille reading system or via the e-mail, which can turn the text using a screen reader software to synthetic voice and large print on the screen (Marsay, 2017). Other formats or services such as British Sign Language and deafblind manual interpreter as well as the speech-to-text reporter also needs to be offered for those who have a hearing loss with or without visual impairments (Marsay, 2017).

Strengths and limitations

The present study provided useful guidance on the necessary steps to develop and assess written health information for patients and specifically the PILs. Methods to address the unmet IN, which information is considered important and to what degree this important this information is. The content the present PIL was generated by patients from the same targeted population which might be more advantageous in comparison with other methods to develop educational materials such as experts and literature reviews (Bolejko et al., 2008). Although the assessments were limited to 20 participants, however, those truly reflected the demographic characteristics of 86 participants in the first study phase such as the age (median age of 64 and 69, respectively), ethnicity (mainly White and Asian), education (diverse educational levels), employment (diverse employment status) and smoking and alcohol consumption (including never, past and current consumers). Similarly, the clinical data were similar between both groups as toward the associated OPMDs, different degrees of OED and a history of cancer. The female gender was, however, slightly underrepresented in the present study compared to the previous phase (20% versus 52%, respectively).

Moreover, most participants found the new leaflet appearance and design as good, its length, quality and volume are about right, helpful, easy to read and understand and had a good understanding of the subject. Also, the presented PIL showed a readability level of the 6th grade and therefore likely to be easy to read by individuals with low health literacy compared to the leaflet produced by the British and Irish Society of Oral Medicine (BSOM, 2016) which was at 9th grade level.

However, the present leaflet remained challenging to read by three patients who indicated a preference to have an Easy Read format of this leaflet. Using leaflets are found to improve the patient's satisfaction with dermatology consultations (Becker et al., 2014) and enthusiasm to attend a 2-month screening for oral cancer (Boundouki et al., 2004). Whether the OED leaflet led to similar outcomes, remain unknown. Also, patients with Black and mixed ethnicities, who participated in phase one of the study, were not represented in the current assessments.

Therefore, oral medicine researchers and clinicians may consider using qualitative methods or patient-reported experience measures (e.g. ODIN-Q), to develop PILs following the national and international guidelines for patient-oriented health information and offer different formats for this information. Afterwards, the outcomes to be assessed over time by qualitative methods and/or self-completed questionnaires in relevance to the patient (e.g. helpfulness, understanding, readability, knowledge and behaviour change), disease outcomes (e.g. whether information led to higher follow-up and early detection of new/recurrent lesions) and clinician-patient communication (e.g. effectiveness of clinical consultations, satisfaction and compliance).

6.5. Conclusion

The present study showed some steps to develop and user-test a new leaflet on OED following the published guidelines to generate written health information for patients and specifically for PILs. A groundwork that lasted three years has led to its needs-based and importance-based content. Both patients and HCPs helped to revise and contribute to a revised version that was at the readability level of 6^{th} grade level. The final version of the leaflet found to be accepted by most of the patients toward its content and design.

The present leaflet can perhaps help to maintain favourable OED outcomes by improving the disease-specific knowledge, highlighting risky behaviours linked to the development of new lesions or MT for the current ones and encouraging early help-seeking for worrisome symptoms. This information can serve as an adjunct and reinforce verbal information to maintain the effectiveness and impact of clinician-patient communication. However, these outcomes were not presently addressed or supported. With the present lack of sufficient online sources of information on OED and OPMDs, the current findings encourage oral medicine clinicians and researchers to produce tailored written health information (e.g. leaflets, booklets and posters) for patients diagnosed with these oral cancer-linked disorders and assess its overtime outcomes related to the patient, disease and patient-clinician communication.

PRACTICAL IMPLICATIONS AND FUTURE DIRECTIONS

The findings from the present project have emphasised the importance of meeting the information needs (IN) of patients with potentially malignant disorders of the mouth and specifically the oral epithelial dysplasia (OED). Future work may consider overcoming the limitations highlighted in each chapter on aspects related to the web-based health information, patient experience measures, validation of ODIN-Q, the patient-clinician concordance, the psychological impact of oral premalignant diseases and developing patient educational materials.

First, further analyses of patient-oriented health information may consider including commercial websites promoted by search engines which are likely to be found on the first searched page (Amaldoss et al., 2015). Similarly, information on social media needs to be included as well due to the growing number of health information seekers and the impact of content on these platforms (Zhao et al., 2017). Examples include the commonly used social network to search health information [e.g. Facebook, Twitter, YouTube and Vimeo] (Wang et al., 2019b) as well as online communities, forums or blogs allied to health [e.g. Patient.info and WebMD]. Future studies may also qualitatively analyse the impact the of the presented OPMDs or OED-related information on adopting healthy behaviours (e.g. smoking cessation and reducing alcohol consumption) and health decision-making (e.g. surgical excision versus watchful waiting for low-risk lesions) (Yan et al., 2019).

Further assessments of online health information may consider other scales to assess accessibility and usability [e.g. LIDA tool (Minervation, 2007)] and quality [e.g. QUality Evaluation Scoring Tool (QUEST) (Robillard et al., 2018), Ensuring Quality Information for Patients (EQIP) (Moult et al., 2004) and the Quality Index for health-related Media Reports (QIMR) (Zeraatkar et al., 2017)] and health literacy [Health Literacy INDEX (Kaphingst et al., 2012)].

Compared to ethnicity and educational background, the low health literacy was a significant factor for the knowledge about cervical cancer prevention (Lindau et al., 2002). Thus, its assessment would be necessary for educational materials of oral cancer-linked disorders. Also, the increased emotional tone in social media was found to be related to an increased extent of cancer-related information (Wang et al., 2019a). Therefore, the sentiment (positive or negative tone) analysis could be relevant to OED-related information to patients. Linguistic Inquiry and Word Count (http://www.liwc.net), SentiStrength (http://sentistrength.wlv.ac.uk) software and the Positive and Negative Affect Schedule questionnaire are generally of choice (Gonçalves et al., 2013, Alessia et al., 2015).

A careful selection and consideration of the limitations of each assessment approach are essential – some of these remain of low reliability or perhaps were not assessed for their intended purpose of use. Furthermore, the developers of web-based health information would need to follow the national [e.g. The Information standard (https://www.england.nhs.uk/tis/) and general data protection regulations (legislation.gov.uk, 2018)] to comply with code of conduct and medico-legal regulations. Also, international initiatives [e.g. eHealth Code of Ethics (Rippen et al., 2000) and the European Quality Criteria for Health Websites (European Commission, 2020)] and certification/accreditation of the content by third-party (subject to charge) organisations [e.g. URAC Accreditation Programmes (https://www.urac.org) and Health On the Net Code certification (https://www.hon.ch/en/)] could be helpful.

Second, there is a need for a systematic review that assesses the methodological quality of the existing IN instruments based on COSMIN's checklists for assessing essential psychometric properties such as reliability, validity and responsiveness (Mokkink et al., 2018a, Prinsen et al., 2018, Terwee et al., 2018).

Third, further psychometric validation of ODIN-Q is required to assess its responsiveness, which reflects the ability of ODIN-Q to ascertain the overtime changes of IN. To ensure that a systematic or random error of ODIN-Q score is not related a true IN change, the measurement error (reliability) needs to be investigated by statistical methods (e.g. Standard Error of Measurement or Smallest Detectable Change) with the recruited cohort remain of a stable condition and appropriate time interval between measurements (de Vet et al., 2011).

Although 'interpretability' is not considered as an essential measurement property (Mokkink et al., 2010a), it is fundamental to draw qualitative interpretations and determine a cut-off level of ODIN-Q scores to indicate individuals with unmet IN about OED - based on a large cohort of patients. It would be equally important to define the floor and ceiling effects as well as the minimal important change/difference which is the smallest, but however subjectively-perceived important change on ODIN-Q score (de Vet et al., 2011). Multi-centre recruitment is needed to maintain a very good sample size (>100 participants and 7 times the number of ODIN-Q items) needed for confirmatory factor analyses [structural validity] (Prinsen et al., 2018). Maintaining a large sample would also help to present the demographic and clinical predictors of reporting unmet IN about OED by regression analyses (Virtanen et al., 1998). Also, individuals with low English language skills, spoken or written, would need to be included through cross-cultural validation of ODIN-Q to their languages.

Regarding the assessment of patient-clinician agreement towards important OED-related information, future research may consider assessing this agreement with the treating clinicians. This would be helpful to examine predictors of high or low agreement related to the patients (e.g. age, gender, education, ethnicity), their disease (e.g. severity, comorbidities and current symptoms) and those of clinicians (e.g. years in practice) and consultation (e.g. length and the number of previous visits). Perhaps a subsequent longitudinal assessment would be feasible to see whether individuals of high agreement with their clinicians would encounter favourable health outcomes compared to those of low or neutral agreement (e.g. lower rates of developing new lesions or malignant transformation). Also, whether a higher agreement on important information would lead to higher patient satisfaction and effective patient-clinician communication.

Moreover, qualitative research remains the most suitable method to investigate the psycho-social impact and subjective experiences of the diagnosis and treatment of precancerous lesions (Green et al., 1998, De Morgan et al., 2002) such as OED. A sub-group analysis is needed based on gender, age, ethnicity and the associated oral premalignant disorder. Some of these subgroups were found to present higher scores for anxiety and depression, dental anxiety and oral health-related quality of life than their counterparts in previous studies (Hittner et al., 2009, Liu et al., 2012, Yang et al., 2018a). A longitudinal assessment could indicate whether these scores would fluctuate along with different phases of care and perhaps help to identify individuals who may require a referral to mental health services (Duffy et al., 2006, Armfield et al., 2013).

Finally, further longitudinal assessment is required to discern if tailored educational interventions (including a patient information leaflet) would contribute to better OED-related information recall and understanding, symptoms interpretation and early detection of new lesions. Cost-effectiveness and cost-consequence financial analyses can be synchronously performed to see if these interventions have improved outcomes related to patients (e.g. disease-related morbidity, quality of life and informed decision-making) and the clinical service (e.g. length of treatment and number of visits/procedures) (Hill, 1997, Gray et al., 2011, McWhirter et al., 2013).

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APPENDICES

Appendix 1. The list of analysed websites for content, quality and readability assessment (n=36)

1) https://maaom.memberclicks.net/index.php?option=com_content&view=article&id=138:premalignant-oral-lesions&catid=22:patient-condition-information&Itemid=120
2) https://publicdocuments.sth.nhs.uk/pil2522.pdf
3) http://oralcancerfoundation.org/cdc/premalignant-lesions/
4) http://about-cancer.cancerresearchuk.org/about-cancer/mouth-cancer/stages-types-grades/types-grades
5) https://www.cancer.org/cancer/oral-cavity-and-oropharyngeal-cancer/about/what-is-oral-cavity-cancer.html
6) http://www.emedicinehealth.com/cancer_of_the_mouth_and_throat/article_em.htm
7) http://www.nyuoralcancer.org/oral_cancer/oral_precancer.html
8) https://www.sixstepscreening.org/oral-cancer/is-it-oral-cancer/
9) https://en.wikipedia.org/wiki/Leukoplakia
10) http://www.netwellness.org/question.cfm/49748.htm
11) http://screening.iarc.fr/atlasoral_list.php?cat=Az&lang=1
12) https://old.cancer.org/acs/groups/cid/documents/webcontent/003128-pdf.pdf
13) http://www.healthcaremagic.com/premiumquestions/Have-epithelial-dysplasia-under-tongue-What-is-it/71831
14) http://www.hopkinsmedicine.org/healthlibrary/conditions/oral_health/oral_cancer_85,P00716/
15) http://www.dermnetnz.org/topics/carcinoma-in-situ-of-oral-cavity/
16) http://www.cancer.ca/en/cancer-information/cancer-type/oral/oral-cancer/precancerous-conditions/?region=on
17) http://www.raysahelian.com/leukoplakia.html
18) http://www.dana-farber.org/uploadedFiles/Library/adult-care/treatment-and-support/centers-and-programs/oral-medicine-and-dentistry/oral-leukoplakia-teaching-sheet.pdf
19) http://www.umiamihospital.com/health-library/oralhlth/specific/cancer
20) http://patient.info/doctor/leukoplakia-pro
21) http://cancer.uc.edu/cancerinfo/TypesOfCancer/MouthNeckThroatCancer/WhatAreOralLesionsPrecancerousandCancerous.aspx
22) https://www.fairview.org/HealthLibrary/Article/84684
23) http://www.cuh.org.uk/addenbrookes-hospital/services/oral-and-maxillofacial-surgery-and-orthodontics/frequently-asked-questions/cancers-mouth-and-face/pre-cancerous-lesions
24) https://www.skinsight.com/skin-conditions/adult/actinic-cheilitis
25) http://timesofindia.indiatimes.com/city/nagpur/Docs-equipped-to-fight-oral-precancer/articleshow/48061213.cms
26) http://www.simplyteeth.com/category/sections/adult/OralMedicineDiseases/WhitePatches.asp?category=adult&section=10&page=73
27) http://www.tampaent.com/conditions-leukoplakia-ent-doctors-wesley-chapel-fl.html
28) http://www.deardoctor.com/inside-the-magazine/issue-28/lichen-planus/
29) http://www.oralcancerawareness.org/precancer.html

30) http://www.veteranshealthlibrary.org/DiseasesConditions/DentalHealth/142,84684_VA
31) http://mouthcancer1.tripod.com/id6.html
32) http://dentalproblems.ygoy.com/2011/10/18/oral-precancer-erythroplakia-overview/
33) https://sites.google.com/site/quitnut/arecapedia/arecancer/oral-precancer
34) http://www.mouthandteeth.com/conditions/leukoplakia.htm
35) https://www.floridahospital.com/oral-cancer/precancerous-oral-conditions
36) http://byebyedoctor.com/leukoplakia/

Appendix 2. The initial generated list for ODIN-Q

Domain 1. Information about the disease

1. General information about OED:
    - Description of the disease nature and process.
    - How common is it?
    - Risk factors.
    - Clinical features of OED.
    - Prevention of OED progression.
    - Screening and early detection of OED.
    - The genetic testing and probability of inheritance of the OED to children – if applicable.
2. The spread and progression of OED:
    - Whether it is contagious or not?
    - The role and mode of transmission of HPV (if applicable)
    - The likelihood of malignant transformation, spread to adjacent structures, or metastasis.
3. The prognosis of OED:
    - The likelihood to cure of OED.
    - The outcome of no treatment or delayed treatment.

Domain 2. Information about investigative tests of OED

1. Options and rationale for the diagnostic procedures.
2. Benefits and risks of the investigative test/s.
3. If a biopsy is needed, what is the amount of tissue/fluid to be removed?
4. The meaning of the test results.

Domain 3. Information about treatments for OED

1. Rationale, options and implications of methods used for disease control (e.g. observation, surgical excision including CO2, chemo-prevention, photodynamic therapy, beta-carotene, lycopene and vitamin A).
2. The procedure and course of each treatment.
3. Benefits and possible side effects of each treatment.
4. Odds of treatment success (cure/recovery rate).
5. Does the choice of one treatment affect the other choices?
6. When and how to know the treatment is working?
7. Medication/s for oral symptoms due to the disease and/or treatment side effects (e.g. pain, ulceration, dry mouth, taste).
8. Self-management.
9. Complimentary or alternative medicine (e.g. acupuncture, herbal medicine).

Domain 4. Physical aspects of OED

1. Disease/treatment effects on daily physical activities (e.g. eating, speaking, maintenance of oral hygiene)
2. Chances and severity of the common symptoms associated with OED (e.g. ulceration, swelling, pain, bleeding, and difficulty of moving the tongue or jaw).
3. Length and frequency of the follow-up.
4. Signs of disease recurrence, spread or development of a new primary lesion.
5. Whether the treatment will change the way they look?

6. How to obtain physical support and advice (e.g. who to contact if the warning signs are observed or immediate help is required)?

Domain 5. Psychosocial aspects of OED

1. Effects of the disease/treatment on psychological wellbeing.
2. Fear of recurrence or progression to cancer.
3. How to handle emotional and cognitive disturbances?
4. The positive aspects in one’s OED experience.
5. Other patients’ experiences about the disease.
6. How to obtain/ask for psychological support and advice?
7. Effects of the disease/treatment on body image and self-esteem.
8. How to cope with changes in appearance, aesthetic and sexual attractiveness (e.g. patients with lip dysplasia).
9. How the disease/treatment may affect social activities (e.g. sports and hobbies)?
10. How the disease/treatment may affect close relationships, family, and friends.

Domain 6. Finances

1. Cost of treatment.
2. Health insurance and eligibility for treatment.
3. Job/career affected by the disease or treatment.
4. Financial support/advice services.

Domain 7. Medical system and access to information about OED

1. Lifestyle adjustment (e.g. tobacco/smoking/alcohol cessation and safe sex).
2. Health promotion (e.g. promoting health literacy?)
3. Exercise.
4. Diet:
    - General nutritional advice.
    - Ways of managing eating and drinking to maintain nutritional intake.
    - Ways of managing swallowing and communication.
5. Information about social support:
    - Community/patient support groups.
    - Spiritual or religious support.
6. Information about the referral process.
7. Information about the experience or qualifications of the specialist and other health care staff.
8. Information about seeking another professional opinion.
9. Information about telephone information services.
10. Information about the current medical research and recruitment for clinical trials.
11. The source of information
    1. One-on-one meeting with one or more of the following:
        - General dental practitioner.
        - OED specialists (i.e. specialists in oral medicine, oral surgery, or ENT).
        - General practitioner.
        - Auxiliary medical staff (medical and dental nurses).
    2. Walk-in help centres.

iii. Printed information materials (e.g. pamphlets, books, magazines, newspapers).
iv. World Wide Web.
v. TV/radio.
vi. DVD/audio recording

Appendix 3. Evaluation forms for the initial versions of ODIN-Q by experts and patients (content and face validity)

1. Evaluation form for ODIN-Q

(experts' version)

Please answer the following questions in the spaces provided, circle or tick the most appropriate options.

Part 1: Background information

1. **Gender** (please tick as necessary): ☐ Male ☐ Female

2. Postgraduate degree in oral medicine:

☐ Higher diploma ☐ Speciality training

☐ MSc/MS ☐ PhD

☐ Others (please specify): ___________________

3. Years in practice (after the first qualification in oral medicine):

☐ less than 2 years ☐ 2-5 years

☐ 6-10 years ☐ More than 10 years

4. Country of practice

☐ UK ☐ USA ☐ Australia

☐ Europe (please specify): ______________ ☐ Others: ___________________

Part 2: Assessment questions for ODIN-Q

Please provide your opinion of the provisional ODIN-Q items by answering the following questions:

- Is the questionnaire **clear**? ☐ **YES** ☐ **NO**

If you answered **NO**, please indicate which question/s you found unclear:

____

____

____

- Do the items **match** the topic (i.e. information needs of patients with oral epithelial dysplasia)? ☐ **YES** ☐ **NO**

If you answered **NO**, please indicate which question/s that doesn't match the topic:

____

____

____

- Are any of the items **redundant/repetitive**? ☐ **YES** ☐ **NO**

If you answered **YES**, please indicate which question/s you found redundant/repeated:

____

____

____

- Do the items in the questionnaire also **seem to be asking about the same general topic**? □ **YES** □ **NO**

If you answered **NO**, please indicate which question/s you found inconsistent:

Evaluation form for ODIN-Q

(patients' version)

After you complete the ODIN-Q, can you please tell us what do you think of the questionnaire in the following section.

- Is the questionnaire **clear**? □ **YES** □ **NO**

If you answered NO, please indicate which question/s you found unclear:

- Is the questionnaire **related** to your condition? □ **YES** □ **NO**

If you answered NO, please indicate which question/s you found unrelated:

- In general, do you find the questionnaire **acceptable**? □ **YES** □ **NO**

If you answered NO, please indicate which question/s you found unacceptable:

Appendix 4. Clinical findings form

Clinical findings form

(To be completed by the clinician as a supplementary to ODIN-Q)

Patient number/code: ____________

❖ **Demographics (other than those noted in the ODIN-Q)**

- Medical history (including other oral disorders):

  ____

- Medications:

  ____

❖ **Date of Diagnosis of oral epithelial dysplasia (OED):**

- The date where the lesion was noticed (if available) ________________.
- Type of biopsy: ☐ excisional ☐ incisional
- The date of 1st diagnosis (by histopathology) ________________.
- If possible, please indicate the type of associated oral condition with OED?

  ☐ Oral leukoplakia ☐ Oral erythroplakia ☐ OLP

  ☐ OSF

  ☐ Chronic hyperplastic candidiasis ☐ Others (please specify): _________

- Current symptoms/signs related to OED ___________________________.

❖ **OED characteristics (instructions: write at the back if multiple):**

- Site: ____________________________
- Size: ____________________________
- Degree:

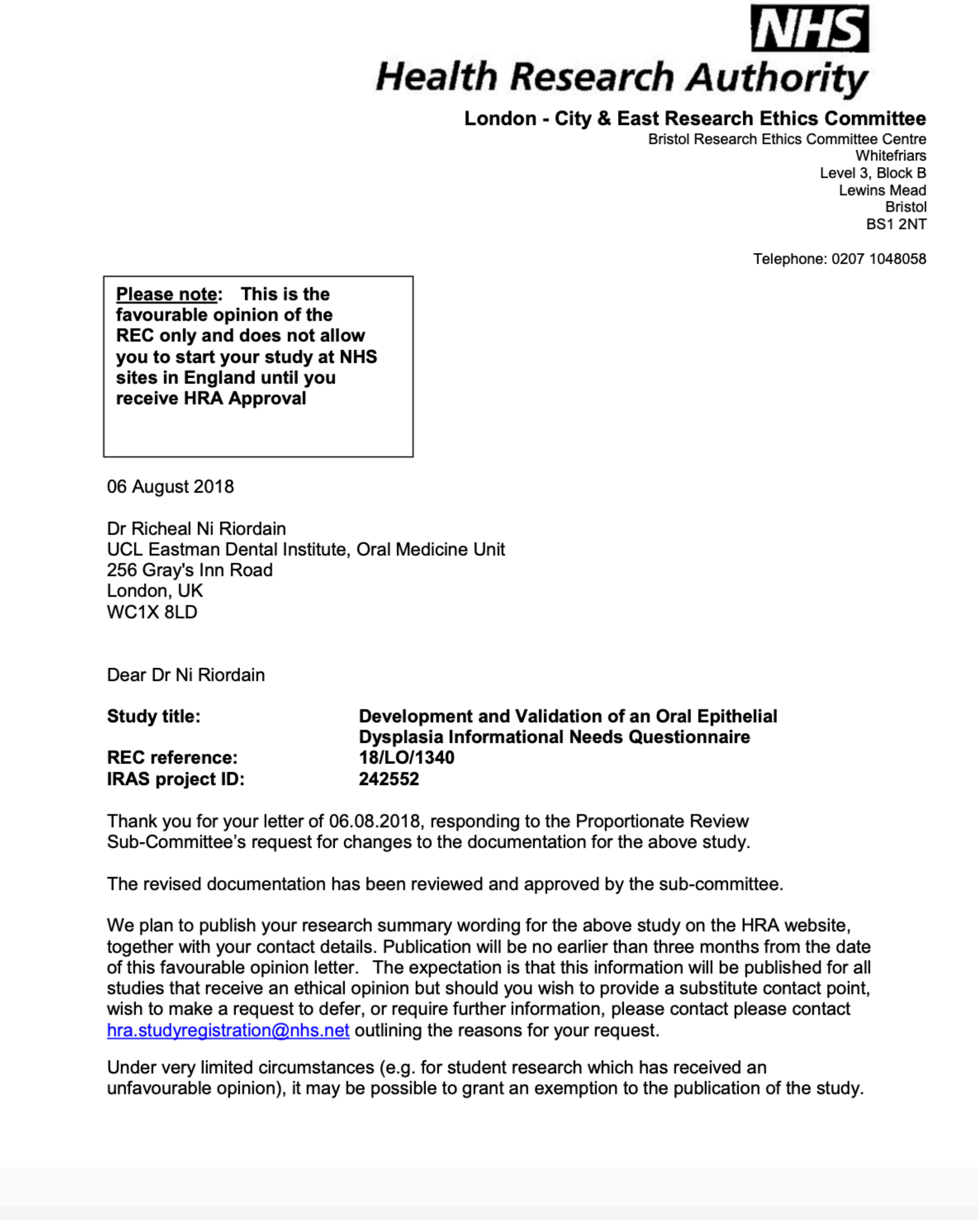
☐ Mild. ☐ Moderate ☐ Severe. ☐ Carcinoma in-situ

- **Type of intervention performed for OED:**

☐ None. ☐ surgical (incl. CO2). ☐ Non-surgical.

☐ Chemo-prevention. ☐ Other (please specify): _________________

Appendix 5. Ethics approvals for ODIN-Q study



NHS
Health Research Authority

London - City & East Research Ethics Committee
Bristol Research Ethics Committee Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 0207 1048058

<u>Please note</u>: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

06 August 2018

Dr Richeal Ni Riordain
UCL Eastman Dental Institute, Oral Medicine Unit
256 Gray's Inn Road
London, UK
WC1X 8LD

Dear Dr Ni Riordain

Study title: **Development and Validation of an Oral Epithelial Dysplasia Informational Needs Questionnaire**
REC reference: **18/LO/1340**
IRAS project ID: **242552**

Thank you for your letter of 06.08.2018, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our RES Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

18/LO/1340	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

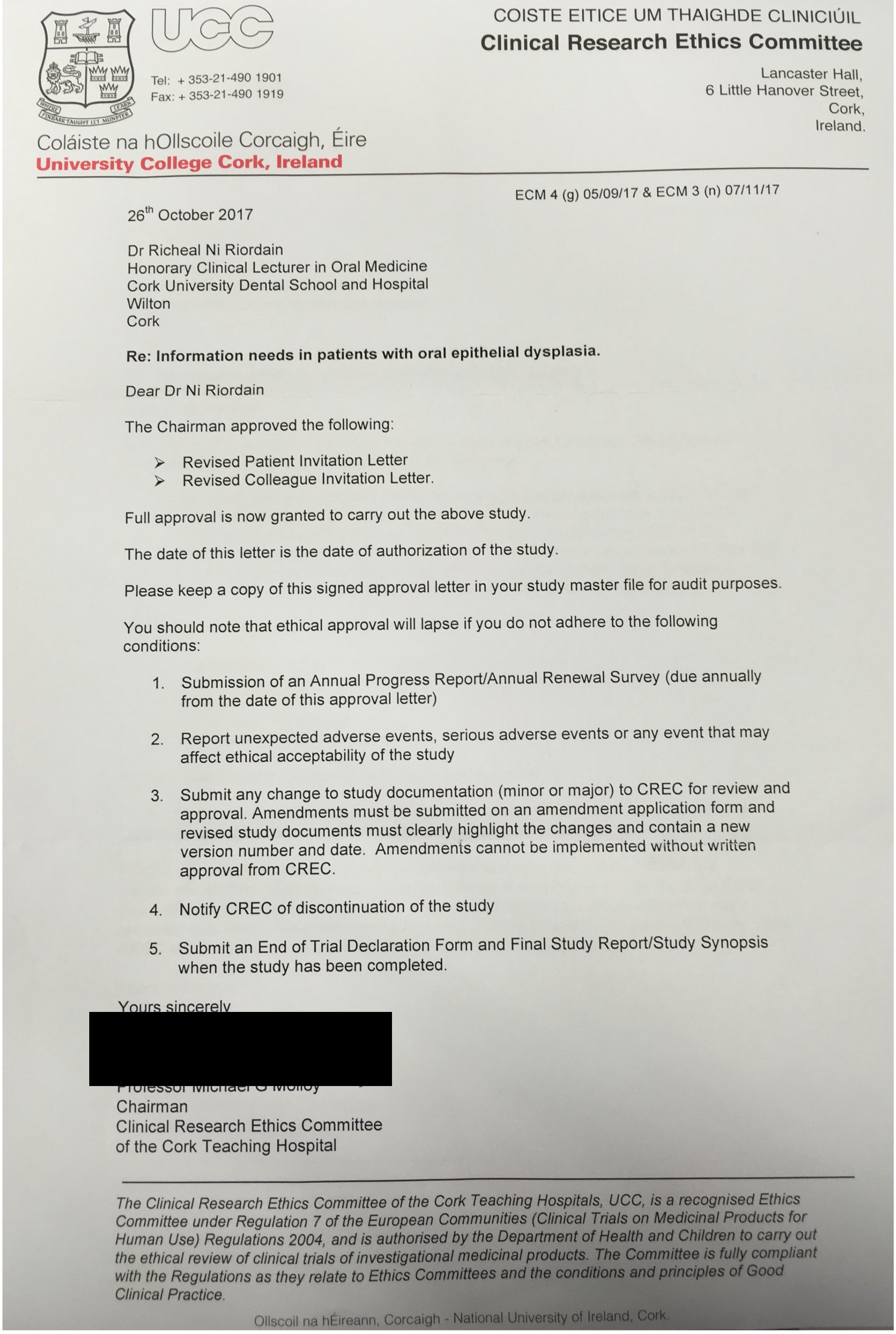
[redacted]

Pp
Dr John Keen
Chair

Email: nrescommittee.london-cityandeast@nhs.net

Copy to: *Misha Ladva*

Ms Rachel Knight, UCL/UCLH joint research office



UCC

Tel: + 353-21-490 1901
Fax: + 353-21-490 1919

Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

COISTE EITICE UM THAIGHDE CLINICIÚIL
Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

ECM 4 (g) 05/09/17 & ECM 3 (n) 07/11/17

26th October 2017

Dr Richeal Ni Riordain
Honorary Clinical Lecturer in Oral Medicine
Cork University Dental School and Hospital
Wilton
Cork

Re: Information needs in patients with oral epithelial dysplasia.

Dear Dr Ni Riordain

The Chairman approved the following:

- Revised Patient Invitation Letter
- Revised Colleague Invitation Letter.

Full approval is now granted to carry out the above study.

The date of this letter is the date of authorization of the study.

Please keep a copy of this signed approval letter in your study master file for audit purposes.

You should note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submission of an Annual Progress Report/Annual Renewal Survey (due annually from the date of this approval letter)
2. Report unexpected adverse events, serious adverse events or any event that may affect ethical acceptability of the study
3. Submit any change to study documentation (minor or major) to CREC for review and approval. Amendments must be submitted on an amendment application form and revised study documents must clearly highlight the changes and contain a new version number and date. Amendments cannot be implemented without written approval from CREC.
4. Notify CREC of discontinuation of the study
5. Submit an End of Trial Declaration Form and Final Study Report/Study Synopsis when the study has been completed.

Yours sincerely

[redacted]

Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospital

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Ollscoil na hÉireann, Corcaigh - National University of Ireland, Cork.

Appendix 6. Participant Information Sheets, Informed Consent Forms and GP letters for both study phases

6.1. Participant Information Sheet for phase 1

Participant Information Sheet

Title project: Development of an Oral Epithelial Dysplasia Informational Needs Questionnaire (ODIN-Q Study, phase1)

Investigators: Dr Richeal Ni Riordain, Professor Stefano Fedele, Professor Stephen Porter, Abdullah Alsoghier (PhD student)

Please read this sheet carefully. Please ask if you do not understand or would like more information

You are being invited to take part in a research study. This is a student research project which will be contributing to a PhD. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

1. What is the purpose of this study?

- Research has showed that patients receiving appropriate and timely information about their disease report less uncertainty and distress, show better compliance and adherence to therapy, are more likely to fully take part in decisions about their own health care, and show increased ability to cope with their disease. It is however difficult for doctors to understand what patients want to know about their disease, as patients' priorities often do not correspond with topics considered important by healthcare professionals.

- In the management of chronic and perhaps cancer-linked disease, a specific standardised questionnaire may overcome this problem. Doctors can use this questionnaire to understand the informational need priorities of individual patients and provide them with tailored and personalised information.

- Using a questionnaire we specifically developed for this condition, we wish to investigate whether your informational needs concerning oral epithelial dysplasia (OED), which you may have experienced since being diagnosed, were met. In the same questionnaire, we will ask you to select the important information aspects that you wish to know. Your responses to this questionnaire will be used to test the suitability of this questionnaire to be used in clinical care for individuals affected by OED.

- Other questionnaire will be used in the current study as to evaluate your desire for active involvement in own health care decisions, and the possible impact on psychological aspects (e.g. anxiety and depression) and quality of life caused by OED.

2. **<u>Why have I been invited?</u>**
    - You have been identified as potential participant by doctors in your clinic because you have been diagnosed with OED.

3. **<u>Do I have to do to take part?</u>**
    - It is up to you to decide whether or not to join the study. If you are interested we will go through this information sheet with you and answer any question you may have regarding the study. You can take as much time as you need to decide if you would like to participate in the study. Even if you agree to take part in the study you are free to withdraw at any time, without giving a reason. This would not affect the standard care you receive in this hospital. Participation in this study will in no way affect your legal rights.

4. **<u>What will happen to me if I take part?</u>**
    - A total of 100 individuals with OED will participate in this part of the study.

    - You will be asked to complete the newly developed Oral Epithelial Dysplasia Informational Needs Questionnaire (ODIN-Q). Also, you will be asked to complete other questionnaires regarding your preferences on involvement in the clinical decision, current anxiety or depression and the potential impact on quality of life.

    - The estimated time needed to complete all questionnaires may last between 20-30 minutes.

    - A randomly selected smaller group of patient will then be asked to complete ODIN-Q one a later day and return the questionnaire by post provided with a prepaid envelop. A second questionnaire will be provided for you to take home and we would ask that you would complete this second questionnaire in 14 days times. A stamped addressed envelope will be provided for you to return the second questionnaire to the hospital.

5. **<u>What will I have to do?</u>**
    - Potential participants will be identified in routine Oral Medicine clinics. If you have been selected as a potential patient for the study we will verbally introduce the study to you and if you are amenable we will provide you with the associated Patient Information Sheet (PIS). You will then be given

adequate time to decide whether to participate further in the study. The inclusion criteria are as follows -
  - A diagnosis of OED as as per current standard diagnostic criteria.
  - Willingness to complete a questionnaire on 2 separate occasions

- You will be invited to complete a newly develop questionnaire about the information needs of patients with OED. This questionnaire will be complete initially at your review appointment in the Eastman Dental Hospital and again 14 days later. We will provide you with a second copy of the questionnaire and a stamped addressed envelope to allow you to return it completed copy to the study group at the Eastman Dental Hospital.

6. **What are the possible alternatives for the treatment**
   - Your treatment will not be altered in anyway by your participation in this study.

7. **What are the possible risks of taking part?**
   - We do no foresee any risks in participating in this research.

8. **Are there any benefits?**
   - We hope that by learning what information patients with OED require we can provide tailored information that may reduce worries or concerns patients have about their health. It may also allow patient to participate more in decisions about their healthcare, as they will be better informed about the risks and benefits of treatments.

9. **What happens when the research study stops?**
   - After we have performed our analysis we can provide you with the results and explain what it means. You will need to continue the regular visits to the Oral Medicine Department at the Eastman Dental Hospital.

10. **What if there is a problem?**
    - Any complaint about the way you have been dealt with during the study will be addressed. The detailed information concerning this is given in the next part of this information sheet. If you have any concerns or complaints you should contact your study doctor in the first instance.

    - University College London (UCL) holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

    - If you are concerned about any aspect of this study, please speak to the researchers who will do their best to answer your questions. Please contact Dr Richeal Ni Riordain (r.niriordain@ucl.ac.uk). If you remain unhappy, you can make a formal complaint through the National Health Service (NHS) complaints procedure. Details can be obtained through the University College London Hospitals (UCLH) Patient Advice and Liaison Service (PALS) on 0207 3447 3041, email: PALS@uclh.nhs.uk, address: PALS, Ground Floor Atrium, University College Hospital, and 235 Euston Road, London, NW1 2BU.

11. How will my information be kept confidential?

- You will be given a unique personal identification code on both copies of the questionnaire. We will store the questionnaire and the code sheet in a locked filing cabinet in a secure magnetic card accessed building. As backup, a second copy will be kept on a password-protected computer. Only researchers associated with the study will have access to completed questionnaires and your code.

- You will not be able to be identified through any of the data and information released from this study.

- All patient information will be treated in the strictest confidence, in accordance with the UK Data Protection Act 2018. UCL is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCL will keep identifiable information about you for 3 years after the study has finished.

- Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

- You can find out more about how we use your information by contacting Dr Richeal Ni Riordain (Chief Investigator) by telephone (+442034567890) or e-mail (r.niriordain@ucl.ac.uk).

12. Who will have access to my information?

- University College London Hospitals (UCLH) will collect information from you and your medical records for this research study in accordance with our instructions.

- UCLH will keep your name, NHS number and contact details confidential and will not pass this information to UCL. UCLH will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. UCL will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

- UCLH will keep identifiable information about you from this study for 3 years after the study has finished.

13. What if new information becomes available?

- Sometimes during the course of a research project, new information becomes available. If this happens, we shall tell you about it and discuss whether you want to continue in the study. If you decide to continue you will be asked to sign an updated consent form.

14. What happens if I decide to withdraw from the study?

- This will not affect your medical care in any way.

15. Will my GP be informed?

- With your consent we would like to inform your GP of your participation in this study by sending a letter.

16. What will happen to the study results?

- The results will be used to perform medical research for publication in medical/scientific journals. We hope that this will help in the management of OED. No details that specifically identify you will be included. We can provide you with details of any publication, at your request.

17. Who is organizing and funding the research

- This study has been designed and organized by senior staff members of the Eastman Dental Institute. The research costs for the study will be supported by a PhD Scholarship of King Saud University, Riyadh, Saudi Arabia. NHS treatment costs [standard and excess] will be supported by UCLH and Service Support Costs via the NIHR Clinical Research Network North Thames.

18. Who has sponsored the study?

- UCL has sponsored the current study. All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favorable opinion by London – City & East Research Ethics Committee.

19. Further information and contact details

- You are encouraged to ask any questions you wish, before, during or after your participation in this study.

Name : Dr Richeal Ni Riordain (Chief Investigator)
Tel : +44(0)2034567890
E-mail : r.niriordain@ucl.ac.uk
Address : 256 Grey’s Inn Road

Eastman Dental Institute, London, WCIX 8LD

Name : Professor Stefano Fedele (Principal Investigator)
Tel : +44 (0) 20 3456 1004
E-mail : s.fedele@ucl.ac.uk
Address : 256 Grey's Inn Road
Eastman Dental Institute, London, WCIX 8LD

Name : Abdullah Alsoghier (student researcher)
Tel : +44 (0) 20 34567890
E-mail : a.alsoghier@ucl.ac.uk
Address : 256 Grey's Inn Road
Eastman Dental Institute, London, WCIX 8LD

Name : University College London Hospitals (UCLH) Patient Advice and Liaison Service (PALS)
Tel : +44 (0) 20 73447 3041
E-mail : PALS@uclh.nhs.uk
Address : Ground Floor Atrium, University College Hospital, 235 Euston Road, London, NW1 2BU.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

6.2. Informed Consent Form for phase 1

INFORMED CONSENT FORM

Title project: Development and Validation of an Oral Epithelial Dysplasia Informational Needs Questionnaire (ODIN-Q Study, phase 1)

Version 2.0 Date 02/08/18

Investigators: Dr Richeal Ni Riordain Professor Stefano Fedele, Professor Stephen Porter, Abdullah Alsoghier (PhD Student)

Please initial here

1.	I confirm that I have read and understood the information sheet dated 02/08/2018 version 2.0 for the above study. I have had the opportunity to consider information, ask questions, and had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am are free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3.	I agree that sections of my medical notes may be looked at by researchers, responsible individuals from regulatory authorities where it is relevant to my taking part in research, the sponsor University College London (UCL), and NHS Trust. I give permission for these individuals to have access to my records.	
4.	I agree to be contacted by letter/phone/email in case researchers need to clarify some information about my health, or using my data and sample already collected for research even though I withdraw from the study. I understand I do not have to agree with this and can withdraw at any time without my medical care being affected.	
5.	I agree to complete the questionnaire on 2 different occasions	
6.	I agree to my GP being informed of my involvement in this study	
7.	I agree to take part in the above study	

Name of patient	Date	Signature
Name of person taking consent (If different from researcher)	Date	Signature
Researcher	Date	Signature

6.3. GP letter for phase 1

Dr Richeal Ni Riordain
Academic Clinical Lecturer
Eastman Dental Institute
256 Gray's Inn Road
London WC1X 8LD
Email: r.niriordain@ucl.ac.uk

IRAS 242552 Version 1.0 Date 10/04/2018

Date:

Dear Dr

Patient name:
Patient DOB:

Patient Address:

The above patient has kindly agreed to participate in a student PhD study UCL investigating the informational needs of patients with oral epithelial dysplasia (ODIN-Q Study).

The patient will be asked to provide his/her information needs concerning oral epithelial dysplasia, which he/she may have experienced since being diagnosed and about his/her preferences of information about this condition using a newly developed questionnaire, ODIN-Q. This new instrument will then undergo psychometric testing to ensure it is valid and reliable for use in a clinical setting.

Yours Sincerely

Dr Richeal Ni Riordain
Chief Investigator

6.4. Participant Information Sheet for phase 2

Participant Information Sheet

Title project: An Assessment of Patient Satisfaction with Information Leaflet on Oral Epithelial Dysplasia (ODIN-Q Study, phase 2)

Investigators: Dr Richeal Ni Riordain, Professor Stefano Fedele, Professor Stephen Porter, Abdullah Alsoghier (PhD student)

Please read this sheet carefully. Please ask if you do not understand or would like more information

You are being invited to take part in a research study.

This is a student research project which will be contributing to a PhD. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

20. What is the purpose of this study?

- Research has showed that patients living with a chronic and potentially malignant disease such as oral epithelial dysplasia (OED) need to be aware of their disease and is provided with the information necessary to maintain their good health. Those who receive appropriate and timely information about their disease report less uncertainty and distress, show better compliance and adherence to therapy, are more likely to fully take part in decisions about their own health care, and show increased ability to cope with their disease.

- Reliable personalized health information can then be provided for patients with OED by their doctors and written health information in the form of leaflets or booklets. It is however difficult for doctors to understand what patients want to know about their disease, as patients' priorities often do not correspond with topics considered important by healthcare professionals.

- We therefore have investigated the informational needs of a group of 100 patients with OED attending UCLH Eastman Dental Hospital in the first phase of the current study (ODIN-Q study, phase 1). Those patients were asked for their unmet information needs since being diagnosed and which aspect of information they believe important to them.

- Using the patients' feedback in phase 1, we developed a patient information leaflet on OED which has been reviewed by specialists, nurses and junior doctors. This study aims to evaluate your satisfaction with how the information leaflet looks, the content of the leaflet and how it is easy to understand the information presented in this leaflet.

- The information presented in leaflets needs to be easy to read and understand. An eye-catching appearance is also important for patients to recall information and may help them make informed decisions about management plan. Further to this, it can make patients more active in their consultations by stimulating questions and raising concerns they may see. Therefore, having your say about the information leaflet about OED is greatly important for us to help in obtaining those benefits.

21. Why have I been invited?

- You have been identified as potential participant by doctors in your clinic because you have been diagnosed with OED.

22. Do I have to do to take part?

- It is up to you to decide whether or not to join the study. If you are interested we will go through this information sheet with you and answer any question you may have regarding the study. You can take as much time as you need to decide if you would like to participate in the study. Even if you agree to take part in the study you are free to withdraw at any time, without giving a reason. This would not affect the standard care you receive in this hospital. Participation in this study will in no way affect your legal rights.

23. What will happen to me if I take part?

- A total of 15 individuals with OED will participate in this part of the study.

- You will be asked to read the information leaflet about OED and provide your opinion about its appearance, length, quality and how easy it is to understand the presented information in a specific form.

- The estimated time needed to read the information leaflet and complete the form may last between 10-15 minutes.

24. What will I have to do?

- Potential participants will be identified in routine Oral Medicine clinics. If you have been selected as a potential patient for the study, we will verbally introduce the study to you and if you are amenable we will provide you with the associated Patient Information Sheet (PIS). You will then be given adequate time to decide whether to participate further in the study. The inclusion criteria are as follows -
  - A diagnosis of OED as per current standard diagnostic criteria.
  - Have no prior participation in phase 1 of the present study (ODIN-Q, phase 1).

- You will be invited to read the information leaflet on OED and provide your opinion about the presented leaflet using a specific form. In this form, you will be given 4 choices to choose for each of the following criteria: appearance and design; length of the content; quality and volume of the information; and how easy the information in the information leaflet was to understand.

25. What are the possible alternatives for the treatment

- Your treatment will not be altered in anyway by your participation in this study.

26. What are the possible risks of taking part?

- We do no foresee any risks in participating in this research.

27. Are there any benefits?

- We hope that by learning about your opinion with information presented in information leaflet we can provide this information to patients with OED that may reduce worries or concerns about their health.

- It may also allow patient to participate more in planning their healthcare, improve his/her experience with clinical care of their disease and focusing the clinical services on what the patient really wish.

28. What happens when the research study stops?

- After we have performed our analysis we can provide you with the results and explain what it means. You will need to continue the regular visits to the Oral Medicine Department at the Eastman Dental Hospital.

29. What if there is a problem?

- Any complaint about the way you have been dealt with during the study will be addressed. The detailed information concerning this is given in the next part of this information sheet. If you have any concerns or complaints you should contact your study doctor in the first instance.

- University College London (UCL) holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

- If you are concerned about any aspect of this study, please speak to the researchers who will do their best to answer your questions. Please contact Dr Richeal Ni Riordain (r.niriordain@ucl.ac.uk). If you remain unhappy, you can make a formal complaint through the National Health Service (NHS) complaints procedure. Details can be obtained through the University College London Hospitals (UCLH) Patient Advice and Liaison Service (PALS) on 0207 3447 3041, email: PALS@uclh.nhs.uk, address: PALS, Ground Floor Atrium, University College Hospital, and 235 Euston Road, London, NW1 2BU.

30. How will my information be kept confidential?

- You will be given a unique personal identification code on both copies of the questionnaire. We will store the questionnaire and the code sheet in a locked filing cabinet in a secure magnetic card accessed building. As backup a second copy will be kept on a password-protected computer. Only researchers associated with the study will have access to completed questionnaires and your code.

- You will not be able to be identified through any of the data and information released from this study.

- All patient information will be treated in the strictest confidence, in accordance with the UK Data Protection Act 2018. UCL is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCL will keep identifiable information about you for 3 years after the study has finished.

- Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

- You can find out more about how we use your information by contacting Dr Richeal Ni Riordain (Chief Investigator) by telephone (+442034567890) or e-mail (r.niriordain@ucl.ac.uk).

31. Who will have access to my information?

- University College London Hospitals (UCLH) will collect information from you and your medical records for this research study in accordance with our instructions.

- UCLH will keep your name, NHS number and contact details confidential and will not pass this information to UCL. UCLH will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. UCL will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

- UCLH will keep identifiable information about you from this study for 3 years after the study has finished.

32. What if new information becomes available?

- Sometimes during the course of a research project, new information becomes available. If this happens, we shall tell you about it and discuss whether you want to continue in the study. If you decide to continue you will be asked to sign an updated consent form.

33. What happens if I decide to withdraw from the study?

- This will not affect your medical care in any way.

34. Will my GP be informed?

- With your consent we would like to inform your GP of your participation in this study by sending a letter.

35. What will happen to the study results?

- The results will be used to perform medical research for publication in medical/scientific journals. We hope that this will help in the management of OED. No details that specifically identify you will be included. We can provide you with details of any publication, at your request**.**

36. Who is organizing and funding the research

- This study has been designed and organized by senior staff members of the Eastman Dental Institute. The research costs for the study will be supported by a PhD Scholarship of King Saud University, Riyadh, Saudi Arabia. NHS treatment costs [standard and excess] will be supported by UCLH and Service Support Costs via the NIHR Clinical Research Network North Thames.

37. Who has sponsored the study?

- UCL has sponsored the current study. All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favorable opinion by London – City & East Research Ethics Committee.

38. Further information and contact details

- You are encouraged to ask any questions you wish, before, during or after your participation in this study.

Name **:** Dr Richeal Ni Riordain (Chief Investigator)
Telp **:** +44(0)2034567890
e-mail **:** r.niriordain@ucl.ac.uk
Address **:** 256 Grey’s Inn Road
Eastman Dental Institute, London, WCIX 8LD

Name **:** Professor Stefano Fedele (Principal Investigator)
Telp **:** +44 (0) 20 3456 1004
e-mail **:** s.fedele@ucl.ac.uk
Address **:** 256 Grey’s Inn Road
Eastman Dental Institute, London, WCIX 8LD

Name **:** Abdullah Alsoghier (student researcher)
Telp **:** +44 (0) 20 34567890
e-mail **:** a.alsoghier@ucl.ac.uk
Address **:** 256 Grey’s Inn Road
Eastman Dental Institute, London, WCIX 8LD

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

6.5. Informed Consent Form for phase 2

INFORMED CONSENT FORM

Title project: An assessment for patient satisfaction with an information leaflet on oral epithelial dysplasia (ODIN-Q Study, phase 2)

Version 1.0 Date 10/04/18

Investigators: Dr Richeal Ni Riordain Professor Stefano Fedele, Professor Stephen Porter, Abdullah Alsoghier (PhD Student)

Please initial here

1.	I confirm that I have read and understood the information sheet dated 01/02/2018 version 1.0 for the above study. I have had the opportunity to consider information, ask questions, and had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am are free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3.	I agree that sections of my medical notes may be looked at by researchers, responsible individuals from regulatory authorities where it is relevant to my taking part in research, the sponsor University College London (UCL), and NHS Trust. I give permission for these individuals to have access to my records.	
4.	I agree to be contacted by letter/phone/email in case researchers need to clarify some information about my health, or using my data and sample already collected for research even though I withdraw from the study. I understand I do not have to agree with this and can withdraw at any time without my medical care being affected.	
5.	I agree to my GP being informed of my involvement in this study	
6.	I agree to take part in the above study	

Name of patient ______________ Date ______________ Signature ______________

Name of person taking consent (If different from researcher) ______________ Date ______________ Signature ______________

Researcher ______________ Date ______________ Signature ______________

6.6. GP letter for phase 2

Dr Richeal Ni Riordain
Academic Clinical Lecturer
Eastman Dental Institute
256 Gray's Inn Road
London WC1X 8LD
Email: r.niriordain@ucl.ac.uk
IRAS 242552 Version 1.0 Date 10/04/2018

Date:

Dear Dr

Patient name:
Patient DOB:

Patient Address:

The above patient has kindly agreed to participate in a student PhD study UCL evaluating the satisfaction with a newly developed information leaflet on oral epithelial dysplasia (ODIN-Q Study, phase 2).

A patient information leaflet on oral epithelial dysplasia was generated using other patients' feedback to an oral epithelial dysplasia information needs questionnaire (ODIN-Q Study, phase 1). The patient will be asked to read the PIL and provide their feedback in an evaluation form about its the appearance, length, quality, comprehension and helpfulness. This new leaflet will then be presented during the regular clinical care for individuals with oral epithelial dysplasia who attend UCLH Eastman Dental Hospital.

Yours Sincerely

Dr Richeal Ni Riordain
Chief Investigator

Appendix 7. The demographic and clinical characteristics for participants for the questionnaire-based study (n=86).

ID	Demographics						Clinical features of OED			
	Gender /age	*Ethnicity*	*Education*	*Employment*	*Smoking*	*Alcohol*	*Date of the first diagnosis*	*Oral condition/ disease*	Number of OED lesions	Site (degree)
101	F/83	White - British	Less than high school	Retired	Never	Never	Dec-15	OL	1	HP (mild)
102	F/38	White - British	Postgraduate degree	*Missing response*	Past	Current	Apr-17	OLP	1	LT (moderate)
103	F/65	White - Any other	Bachelor's degree	Retired	Never	Never	Jan-14	OL	1	LT (severe)
104	F/62	White - British	Bachelor's degree	*Missing response*	Past	Current	Dec-12	OLP	1	LT (severe)
105	F/64	White - British	Less than high school	Retired	Never	Current	Apr-07	OLP	1	LT (moderate)
106	M/76	Asian or Asian British - Pakistani	Bachelor's degree	Retired	Never	Never	Nov-16	OLP	1	HP/SP (moderate)
107	F/67	Asian or Asian British - Indian	Less than high school	Retired	Never	Current	Jul-08	OSF	1	BM (mild)
108	F/71	White - British	Some college	Retired	Never	Never	Jun-15	OLP	1	BM (moderate)
110	M/89	White - British	Postgraduate degree	Retired	Past	Current	Oct-15	OLP	1	BM (mild to moderate)
111†	M/65	Asian or Asian	Some college	Employed full-time	Never	Never	Jun-12	OLP/OL	1	DT (moderate to severe)

		British - Indian								
112	M/60	White - British	Some college	Retired	Past	Current	Dec-06	OLP	2	BM (severe), MaxG (moderate to severe)
113	F/84	White - Any other	None	Retired	Never	Never	Jul-08	None	1	SP (mild)
114	M/55	White - British	High school diploma	Self-employed	Past	Current	Mar-12	None	1	BM/ ManG (mild)
115	F/57	White - Any other	Postgraduate degree	Employed full-time	Current	Current	Dec-01	OL	1	HP (mild)
117	F/45	Asian or Asian British - Pakistani	Some college	Unemployed	Never	Never	Apr-16	VL	1	ManG (mild)
118	M/83	White - British	Less than high school	Retired	Past	Current	Aug-13	None	1	LT/VT (mild to moderate)
119	F/60	Asian or Asian British - Indian	Less than high school	Self-employed	Never	Never	Nov-12	OLP	1	BM (mild)
120	M/66	White - British	Postgraduate degree	Employed full-time	Past	Current	Jan-16	OLP	1	ManG (mild to moderate)
121	M/65	White - British	Some college	Retired	Past	Current	Feb-15	OLP	1	LT (mild)
122	F/61	White - British	Postgraduate degree	Self-employed	Never	Current	Feb-18	OLP	2	LT (severe, mild)
124	M/79	White - British	Bachelor’s degree	Retired	Past	Current	Jul-17	OL	1	LT (mild)
125	F/59	White - British	Bachelor’s degree	Self-employed	Past	Current	Jan-14	OLP	1	BM (mild to moderate)
126	M/31	White - Any other	Postgraduate degree	Employed full-time	Past	Current	Oct-18	OLP	1	LT (mild to moderate)

127	M/73	White - British	Less than high school	Retired	Current	Never	Jul-08	None	1	OralComm (mild)
128	M/61	White - British	Postgraduate degree	Retired	Never	Never	Jul-16	OLP	1	BM (mild)
129	M/76	Asian or Asian British - Any Other	High school diploma	Retired	Never	Never	Oct-15	None	1	LT (mild to moderate, mild)
130	M/66	White - Any other	Bachelor’s degree	Employed full-time	Never	Current	Jun-16	None	1	LT (mild to moderate)
131	F/56	White - British	Some college	Unemployed	Current	Never	Nov-12	Melamine incontinence/ smoker’s melanosis	1	SP (mild)
132[†]	F/75	White - British	*Missing response*	Retired	Past	Never	Mar-09	OLP	4	LT (severe, severe, severe, severe)
134[†]	F/83	White - Irish	Less than high school	Retired	Past	Never	Jan-17	OLP	2	LT (mild to moderate), VT (mild)
136	F/68	White - British	Some college/dip in higher education	Retired	Past	Never	Oct-18	Imm.sup	2	LT (moderate, severe)
137	M/53	White - British	Some college	Employed full-time	Past	Current	Jan-13	None	1	LT (mild)
139	F/55	Black or Black British - African	Postgraduate degree	Unemployed	Past	Past	Sep-18	Chronic trauma	1	BM (mild)
141	F/63	White - British	Bachelor's degree	Employed part-time	Past	Current	Apr-18	None	1	OralComm (mild)
143	M/70	White - British	Postgraduate degree	Retired	Past	Current	Dec-12	OL	1	ManG (mild to mod)

144	M/55	White - British	Some college	Employed full-time	Never	Current	Jan-07	OLP	1	LT (mild)
145	M/68	Asian or Asian British - Indian	Some college	Retired	Past	Current	Jun-11	None	1	BM (mild)
146	M/75	White - Any other	*Missing*	Self-employed	Past	Current	Jun-11	None	1	BM (mild)
147	M/65	White - Any other	White - any other	Retired	Past	Past	Jun-07	OLP/LR	5	BM (Moderate, mild, mild-moderate, mild, mild)
148	M/75	White - British	Postgraduate degree	Retired	Never	Current	Apr-16	None	2	LT (mild to moderate, mild-moderate)
149	F/74	White - British	Secondary school	Retired	Never	Never	Oct-17	OLP	1	LT (severe)
150	F/68	White - British	Some college	Retired	Past	Current	Jan-06	CHC, OLP	1	LT (mild)
151	M/55	White - Any other	High school diploma	Employed full-time	Past	Current	Feb-12	OE	2	LT (mild), HP (mild)
152	F/68	White - British	*Missing*	Retired	Past	Never	Dec-12	OL	2	ManG (mild), HP (mild)
153	M/64	Black or Black British - African	Some college	Retired	Never	Never	Jul-13	OLP/LR	1	LL (mild)
155	F/73	Asian or Asian British - Any other	Less than high school	Other: housewife	Past	Never	Dec-03	OLP, OC	1	BM (moderate)
157	M/75	White - British	Postgraduate degree	Retired	Past	Current	Jul-14	None	3	VT (mild), LT (moderate to severe, mild-moderate)

158	F/54	White - Any other	High school diploma	Self-employed	Never	Current	Mar-18	None	2	VT (mild to moderate), LT (mild to moderate)
159	F/71	Asian or Asian British - Indian	Less than high school	Retired	Current	Past	Feb-13	OLP, CHC	1	LT (mild)
160	F/70	Asian or Asian British - Indian	High school diploma/ some college	Retired	Never	Never	Apr-18	OLP	2	BM (severe, mild)
161	F/66	White - British	Some college	Self-employed	Past	Current	Jul-15	None	1	MaxG (mild)
162	M/63	White - British	Some college	Retired	Past	Current	Oct-04	None	1	BM (mild)
163	M/40	Asian or Asian British - Pakistani	Postgraduate degree	Employed full-time	Current	Never	Jun-12	VL	2	SP (mild), HP (mild)
164	F/74	White - Any other	Bachelor's degree	Retired	Current	Current	Jun-14	None	3	FOM (mild, mild to moderate), VT (moderate-severe)
165	M/84	White - British	Bachelor's degree	Retired	Past	Current	Jul-11	OLP, CHC	1	LT (mild)
166	M/65	Mixed - White and Asian	Bachelor's degree	Self-employed	Past	Current	Jun-96	OLP	1	VT/LT (mild)
167[†]	F/73	White - British	Some college	Retired	Past	Past	Nob-15	None	3	LT (mild to moderate, mild to moderate, mild)
168	M/68	White - British	*Missing*	Retired	Past	Current	Feb-16	OC	2	LT (mild, mild)
169	M/64	White - Any other	Postgraduate degree	Self-employed	Past	Current	Aug-11	MMP, DG	2	MaxG (moderate), ManG (mild to moderate)

171	F/63	White - British	Less than high school	Retired	Current	Current	Jul-15	Multifocal OL	2	FOM (moderate to severe), ManG (severe)
172	F/58	White - British	High school diploma	Retired	Past	Current	Oct-16	Dermatomy-ositis, OLP, OC, recurrent HSV keratitis	1	LT (moderate)
173	F/63	Asian or Asian British - Any Other	Postgraduate degree	Postgraduate	Never	Never	Jan-13	CHC, OLP	5	LT (mild, moderate, mild, mild, mild to moderate)
175	M/65	White - British	Less than high school	Retired	Past	Current	Jul-13	OL	1	LL (mild to moderate)
176	M/74	White - British	Bachelor's degree	Retired	Never	Current	Jul-13	OC	2	VT (mild to moderate), LT (mild to moderate,)
177	M/53	Asian or Asian British - Indian	High school diploma	Employed full-time	Past	Current	Jan-16	CHC	1	BM (mild)
180	F/77	White - British	Less than high school	Retired	Past	Past	Dec-15	OLP	2	LT (moderate to severe, moderate)
181	F/67	Asian or Asian British - Pakistani	Less than high school	Retired	Past	Never	Oct-13	OSF	1	BM (mild)
182	M/58	Asian or Asian British - Any other	High school diploma	Employed	Past	Current	Oct-18	OSF	2	LT (moderate, mild to moderate)
183	F/68	White - British	Some college	Retired	Past	Never	Nov-11	OLP	3	ManG/labial sulcus (severe, mild to moderate, mild)

184	F/66	White - British	Bachelor's degree	Retired	Past	Current	Feb-09	OLP, VL	2	BM (moderate, moderate)
187	M/65	White - British	Postgraduate degree	Retired	Past	Current	Jul-03	HIV, HPV, multifocal OL	13[1]	BM (5X severe), HP (severe), LT (3X severe, mild, mild), VT (severe), retromolar region (severe)
188	F/53	White - British	*Missing*	Employed part-time	Never	Current	Jul-10	None	3	VT (severe, severe), LT (moderate to severe)
189	M/65	White - British	Some college	Retired	Past	Past	Oct-07	VL	3	BM (mild), LT (mild, mild-moderate)
190	M/81	White - British	Postgraduate degree	Retired	Never	Past	Feb-16	OL	1	HP/SP (mild)
191	F/79	White - British	High school diploma	Retired	Past	Never	Mar-11	Smoker's keratosis	1	LT (mild)
192	M/45	White - British	Bachelor's degree	Employed full-time	Past	Current	Jul-19	VL	2	FOM (moderate to severe), VT (moderate to severe)
194	F/40	White - Any other	Bachelor's degree	Self-employed	Past	Current	Jul-19	OL	4	FOM (severe, moderate, moderate), LT/ManG (moderate to severe)
195	M/77	Asian Or Asian British - Any other	High school diploma	Retired	Never	Never	Oct-07	None	2	FOM (mild), Retromolar region (moderate)
196	M/74	White - Any Other	Other: speciality certificate	Retired	Current	Current	Apr-19	VL	1	HP/SP (moderate)
197	F/71	White - British	Other: speciality/ professional degree	Self-employed	Never	Current	Aug-11	OLP	1	VT (severe)

201	M/55	White - Any other	High school diploma	Employed full-time	Current	Current	Nov-06	HPV	1[‡]	LL (mild to moderate)
203	F/77	White - British	Some college	Other	Never	Current	Dec-06	OLP/LR	1	LL (mild)
204	F/60	White - British	Bachelor's degree	Retired	Past	Current	Aug-14	OL	1	LT (mild)
205	F/46	White - Any other	Bachelor's degree	Employed full-time	Never	Current	Aug-17	VL	1	ManG (mild to moderate)
206	F/58	White - British	High school dip/ some college	Retired	Past	Current	Feb-17	OLP/LR	1	DT (mild)
207	F/66	White - Any other	Postgraduate degree	Retired	Never	Current	Jun-18	LR	1	BM (mild)

*****_In a typical day._

†The participant did complete only ODIN-Q.

[‡] _HPV-associated (koilocytic) OED_

Abbreviations

1. Gen, *Gender;* ***M****, male;* ***F****, female*

2. Oral condition/disease: AC*, actinic cheilitis;* ***CHC****; chronic hyperplastic candidosis;* ***DG****, desquamative gingivitis;* ***Imm.sup****, immunosuppression;* ***LR****, lichenoid reaction;* ***MMP****, mucous memberane pemphigoid;* ***OE****; oral erythroplakia;* ***OC****; oral candidosis;* ***OL****, oral leukoplakia;* ***OLP****, oral lichen planus;* ***VL****; verrucous leukoplakia*

3. Sites of dysplasia: BM, *buccal mucosa;* ***DT****, dorsum of the tongue;* ***FOM****, floor of the mouth;* ***HP****, hard palate;* ***LT****, lateral tongue;* ***LL****, lower lip;* ***ManG****: mandibular gingiva;* ***MaxG****, maxillary gingiva;* ***OralComm****, oral (labial) commissure;* ***SP****, soft palate;* ***VT****, ventral tongue.*

Appendix 8. The 33-item ODIN-Q (version 3.0)

Oral Epithelial Dysplasia Informational Needs Questionnaire (ODIN-Q)

To ensure making informed decisions, and to help us plan better services for people affected by oral epithelial dysplasia (OED), **we are interested to know whether your information needs, which you may have experienced since being diagnosed, have been met and your preferences of information about OED.**

At section 1, please **fill/tick** that best describes your **background information**.

1. Background information

Please answer the following questions in the spaces provided, circle or tick the most appropriate options.

1. Age: _________

2. Gender (please tick as necessary): ☐ Male ☐ Female

3. Ethnicity:

A. White

- ☐ White - British
- ☐ White - Irish
- ☐ White - Any other White background

B - Mixed

- ☐ Mixed - White and Black Caribbean
- ☐ Mixed - White and Black African
- ☐ Mixed - White and Asian
- ☐ Mixed - Any other mixed background

C – Asian or Asian British

D – Black or Black British

☐ Asian or Asian British - Indian

☐ Asian or Asian British - Pakistani

☐ Asian or Asian British - Bangladeshi

☐ Asian or Asian British - Any other Asian background

☐ Black or Black British - Caribbean

☐ Black or Black British - African

☐ Black or Black British - Any other Black background

E – Chinese or other ethnic group

☐ Chinese

☐ Any other ethnic group

4. Educational level:

☐ Less than high school ☐ Bachelor’s degree ☐ High school diploma

☐ Postgraduate degree ☐ Some college ☐ Other (please describe): ______

5. Employment status:

☐ Student ☐ Employed full-time ☐ Employed part-time

☐ Self-employed ☐ Retired ☐ Other (please specify): ______

6. Smoking:

☐ Never smoke ☐ Past smoker ☐ Current smoker

<u>If choose current smoker, please tick one or more of the following:</u>

☐ Chewed tobacco (Type?): _________ ☐ Cigarettes (number/day): _________

☐ Other (Please specify): ________

7. Alcohol:

☐ Never drink ☐ Past drinking ☐ Current drinking.

<u>If you have indicated that you are currently drinking, can you specify how many units of alcohol do you have on a typical day when you are drinking?</u>

☐ 1-2 units a day ☐ 3-4 units ☐ 5-6 units ☐ 7-8 units ☐ 9 or more units

* Please refer to the NHS website for further information about alcohol units https://www.nhs.uk/Livewell/alcohol/Pages/alcohol-units.aspx

2. Information needs in oral epithelial dysplasia (OED)

For **every item** on the following pages, please rate '**the amount of information you received since being diagnosed'** and '**is this item important to you?** on a scale from 1 to 4. If you are unsure about how to answer a question, give **the best answer** you can.

For example:

Information about the disease	Amount of information received since being diagnosed:				Is this item important to you?			
1. How common the disease is?	☐Too much	☑Enough	☐Not enough	☐None	☑Very	☐Yes	☐Not very	☐Not at all

If you answered as we have, it means you have received **'enough'** information about how common the disease is, and it is **'very'** important for you to know.

Tick only one box for each section

Information about the disease	Amount of information received since being diagnosed:				Is this item important to you?			
1. What oral epithelial dysplasia (OED) is?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
2. How common is it?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
3. What are the risk factors for developing it?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
4. How it looks in the mouth or lips?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
5. Whether it is contagious or not?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
6. About the role of human papilloma virus.	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
7. About the disease grades and risk of developing mouth cancer.	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
8. What will happen if I continue to smoke or drink alcohol?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
9. What is a safe level of alcohol to drink?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
10. What is likely to happen to OED in the future?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all

Information about investigative tests of OED	Amount of information received since being diagnosed:				Is this item important to you?			
11. About the screening and early detection.	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all

12. About the genetic testing and chance of inheritance to children (if applicable).* **Deleted item*	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
13. What are the benefits, risks, how each test works, and the meaning of test results?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all

Information about treatments for OED	Amount of information received since being diagnosed:				Is this item important to you?			
14. What will happen if it is not treated?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
15. About treatment options, benefits, risks, and how each treatment works?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
16. How the disease/treatment may affect the quality of life?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
17. About self-management at home.	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
18. About complementary and alternative medicine (e.g. herbal medicine).	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
19. What are the chances of a cure?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all

Physical aspects of OED	Amount of information received since being diagnosed:				Is this item important to you?			
20. How frequent and severe are the symptoms (e.g. ulceration, swelling, or bleeding)?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
21. About chances of spreading to adjacent or distant body part?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
22. About the effects of the disease/treatment on daily physical activities (e.g. eating, speaking, or maintenance of oral hygiene).	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
23. About the diet and nutrition.	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all

Psychosocial aspects of OED	Amount of information received since being diagnosed:				Is this item important to you?			
24. About the fear of progression to cancer.	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
25. How to cope with the possible effects of the disease/treatment?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
26. How the disease/treatment may affect social life (e.g. close relationships, family, and friends)?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all

Medical system and access to information about OED	Amount of information received since being diagnosed:				Is this item important to you?			
27. How the disease /treatment may affect my job/ career?* **Deleted item*	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
28. About the experience of your doctor and other health care staff.	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
29. About seeking another professional opinion.	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
30. How to obtain physical support and advice (e.g. who to contact if the warning signs appear)?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
31. How to obtain psychological support and advice?	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
32. About community/ patient support groups.	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
33. About health promotion (e.g. promoting one’s health literacy).	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
34. About the lifestyle adjustment (e.g. tobacco and alcohol cessation, and safe sex).	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all
35. About the research and recruitment for clinical trials.	☐Too much	☐Enough	☐Not enough	☐None	☐Very	☐Yes	☐Not very	☐Not at all

- Please **circle** your **one or more choice** to receive information from with regard to OED:

1. One-on-one meeting
2. Walk-in help centre
3. Group information session
4. Printed information materials (e.g. pamphlets, books, magazines, newspapers)
5. World Wide Web
6. TV/radio
7. DVD/audio recording

- If you have selected **'One-on-one meeting'**, please **rank** the health care professionals that you want to receive the information from (from 1 to 4):
    - a. General dental practitioner ___
    - b. General practitioner___
    - c. OED specialists (e.g. specialists in oral medicine, oral surgery, or ENT) ___
    - d. Auxiliary medical staff (e.g. medical or dental nurses) ___

- Please indicate other topics not included in the list.

____

____

____

For further information please contact:

Dr Richeal Ni Riordain

UCL Eastman Dental Institute

256 Gray's Inn Road, London, WC1X 8LD

r.niriordain@ucl.ac.uk

Tel: +44 (0) 20 7916 1004

Appendix 9. Invitation letter for clinicians (concordance study)

An invitation for a questionnaire study - your thoughts on the patient's informational needs concerning oral epithelial dysplasia

Dear Colleague,

I would much value your help with a project that one of our PhD students is undertaking. He is looking to determine the information needs of individuals who have been found to have oral epithelial dysplasia (OED).

There is evidence that on-line resources for patients with OED are limited (https://www.sciencedirect.com/science/article/pii/S1368837518301878) and this wish to develop a more robust information resource. As part of this we will be asking patients (when we have ethical approval their thoughts), but before this, **I would value your thoughts (as a clinician who look after patients with OED) as to what extent you think that your patient with OED will rate their need for certain information.**

Thus if possible could you complete the enclosed questionnaire. I am hoping that it will not take you too long (it took me about 4 minutes).

Kindly return the completed questionnaire to the congress's reception.

Yours sincerely,

Appendix 10. The clinician's version of ODIN-Q

Oral Epithelial Dysplasia Informational Needs Questionnaire – Clinician's version

To ensure making informed decisions, and to help us plan better services for people affected by oral epithelial dysplasia (OED), **we are interested to know your thoughts about information needed by patients regarding OED.**

Thus, the aim of this survey to assess the concordance between clinicians (i.e. yourself) and patients regarding the degree of importance of certain informational aspects about OED.

Part 1: Background information

At this section, please **fill/tick** that best describes your background information.

1. **Gender** (please tick as necessary): ☐ Male ☐ Female

2. Postgraduate degree:

☐ Higher diploma ☐ Speciality training ☐ MSc/MS

☐ PhD

☐ Others (please specify): ___________________

3. Speciality:

☐ Oral medicine ☐ Oral surgery ☐ Others (please specify):

____

4. In an average month, how many patients with OED you regularly see?

☐ Less than 5 patients ☐ 5-10 patients ☐ Between 10-20 patients ☐ More than 20 patients

5. Years in practice as specialist:

☐ less than 5 years ☐ 5-10 years ☐ 10-15 years ☐ More than 20 years

6. Country of practice:

☐ UK ☐ USA ☐ Australia ☐ Others:

____

Part 2. Patients' information needs concerning oral epithelial dysplasia

For every item on the following pages**, please rate how important an item is to your patient on a 4-point scale (from very to not at all).**

If you are unsure about how to answer a question, give the best answer you can.

An example is provided here:

Q. What are the risk factors for developing the disease?

- **Very important**
- Important
- Not very important
- Not at all important

If you answered as we have, it means you have believed that your patient/s would rate receiving information about risk factors as **'very important'.**

Tick only one box for each section

Information about the disease	Is this item important to your patient?			
1. What oral epithelial dysplasia (OED) is?	☐Very important	☐Important	☐Not very important	☐Not at all important
2. How common is it?	☐Very important	☐Important	☐Not very important	☐Not at all important
3. What are the risk factors for developing it?	☐Very important	☐Important	☐Not very important	☐Not at all important
4. How it looks in the mouth or lips?	☐Very important	☐Important	☐Not very important	☐Not at all important
5. Whether it is contagious or not?	☐Very important	☐Important	☐Not very important	☐Not at all important
6. About the role of human papilloma virus.	☐Very important	☐Important	☐Not very important	☐Not at all important
7. About the disease grades and risk of developing mouth cancer.	☐Very important	☐Important	☐Not very important	☐Not at all important
8. What will happen if continues to smoke or drink alcohol?	☐Very important	☐Important	☐Not very important	☐Not at all important
9. What is a low-risk drinking level of alcohol?	☐Very important	☐Important	☐Not very important	☐Not at all important
10. What is likely to happen to OED in the future?	☐Very important	☐Important	☐Not very important	☐Not at all important

Information about investigative tests of OED	Is this item important to your patient?			
11. About the screening and early detection.	☐Very important	☐Important	☐Not very important	☐Not at all important
12. About the genetic testing and chance of inheritance to children (if applicable).	☐Very important	☐Important	☐Not very important	☐Not at all important
13. What are the benefits, risks, how each test works, and the meaning of test results?	☐Very important	☐Important	☐Not very important	☐Not at all important

Information about treatments for OED	Is this item important to your patient?			
14. What will happen if it is not treated?	☐Very important	☐Important	☐Not very important	☐Not at all important
15. About treatment options, benefits, risks, and how each treatment works.	☐Very important	☐Important	☐Not very important	☐Not at all important
16. How the disease/treatment may affect the quality of life?	☐Very important	☐Important	☐Not very important	☐Not at all important
17. About self-management at home.	☐Very important	☐Important	☐Not very important	☐Not at all important
18. About complementary and alternative medicine (e.g. herbal medicine).	☐Very important	☐Important	☐Not very important	☐Not at all important

Physical aspects of OED	Is this item important to your patient?			
19. How frequent and severe are the symptoms (e.g. ulceration, swelling, or bleeding)?	☐Very important	☐Important	☐Not very important	☐Not at all important

20. About chances of spreading to adjacent or distant body part.	☐Very important	☐Important	☐Not very important	☐Not at all important
21. About the effects of the disease/treatment on daily physical activities (e.g. eating, speaking, or maintenance of oral hygiene).	☐Very important	☐Important	☐Not very important	☐Not at all important

Psychosocial aspects of OED	Is this item important to your patient?			
22. About the fear of progression to cancer.	☐Very important	☐Important	☐Not very important	☐Not at all important
23. How to cope with the possible effects of the disease/treatment?	☐Very important	☐Important	☐Not very important	☐Not at all important
24. How the disease/treatment may affect social life (e.g. close relationships, family, and friends)?	☐Very important	☐Important	☐Not very important	☐Not at all important
25. How the disease/treatment may affect their job/career (if applicable)?	☐Very important	☐Important	☐Not very important	☐Not at all important

Medical system and access to information about OED	Is this item important to your patient?			
26. About the experience of your doctor and other health care staff.	☐Very important	☐Important	☐Not very important	☐Not at all important
27. About seeking another professional opinion.	☐Very important	☐Important	☐Not very important	☐Not at all important
28. How to obtain physical support and advice (e.g. who to contact if the warning signs appear)?	☐Very important	☐Important	☐Not very important	☐Not at all important
29. How to obtain psychological support and advice?	☐Very important	☐Important	☐Not very important	☐Not at all important
30. About community/patient support groups.	☐Very important	☐Important	☐Not very important	☐Not at all important

31. About health promotion (e.g. promoting one's health literacy).	☐Very important	☐Important	☐Not very important	☐Not at all important
32. About the lifestyle adjustment (e.g. tobacco and alcohol cessation, and safe sex).	☐Very important	☐Important	☐Not very important	☐Not at all important
33. About the research and recruitment for clinical trials.	☐Very important	☐Important	☐Not very important	☐Not at all important

Please provide any comments below:

____

____

____

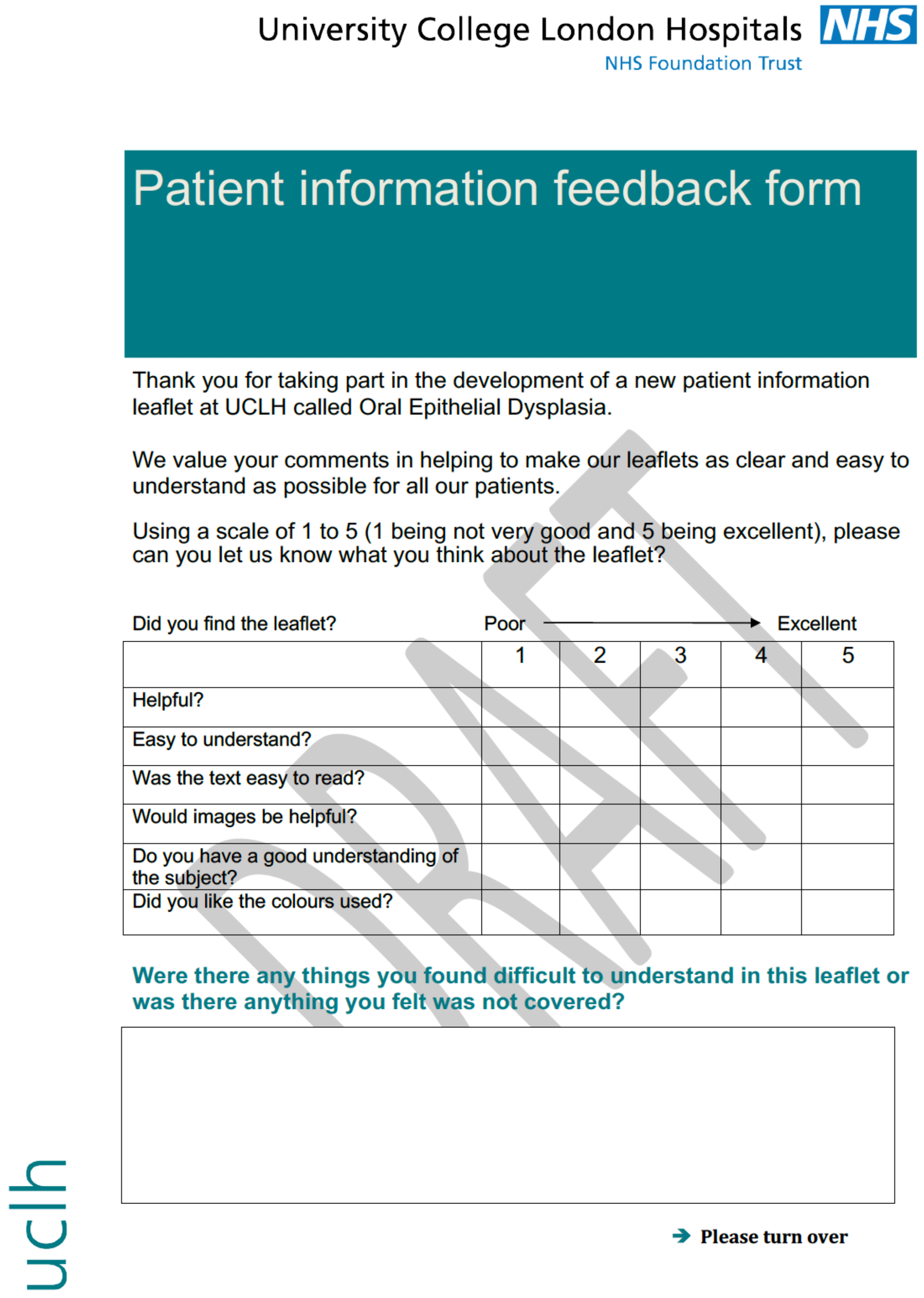
Appendix 11. The satisfaction and Helpfulness with a Patient Information Leaflet Evaluation Form (Robertson et al., 2002)

Satisfaction and Helpfulness with a Patient Information Leaflet

After reading the information leaflet about your condition, can you tell us what do you think about it?

1. What do you think about the appearance and design of this leaflet?	☐ Very good ☐ Good ☐ Poor ☐ Very poor
2. What do you think about the length of its content?	☐ Too long ☐ About right ☐ Too short
3. What do you think about quality and volume of the information?	☐ Too much ☐ About right ☐ Too little
4. How easy the information was to understand	☐ Very difficult ☐ Quite difficult ☐ Quite easy ☐ Very easy

Appendix 12. The UCLH Patient Information Feedback Form.



University College London Hospitals NHS
NHS Foundation Trust

Patient information feedback form

Thank you for taking part in the development of a new patient information leaflet at UCLH called Oral Epithelial Dysplasia.

We value your comments in helping to make our leaflets as clear and easy to understand as possible for all our patients.

Using a scale of 1 to 5 (1 being not very good and 5 being excellent), please can you let us know what you think about the leaflet?

Did you find the leaflet? Poor → Excellent

	1	2	3	4	5
Helpful?					
Easy to understand?					
Was the text easy to read?					
Would images be helpful?					
Do you have a good understanding of the subject?					
Did you like the colours used?					

Were there any things you found difficult to understand in this leaflet or was there anything you felt was not covered?

→ **Please turn over**

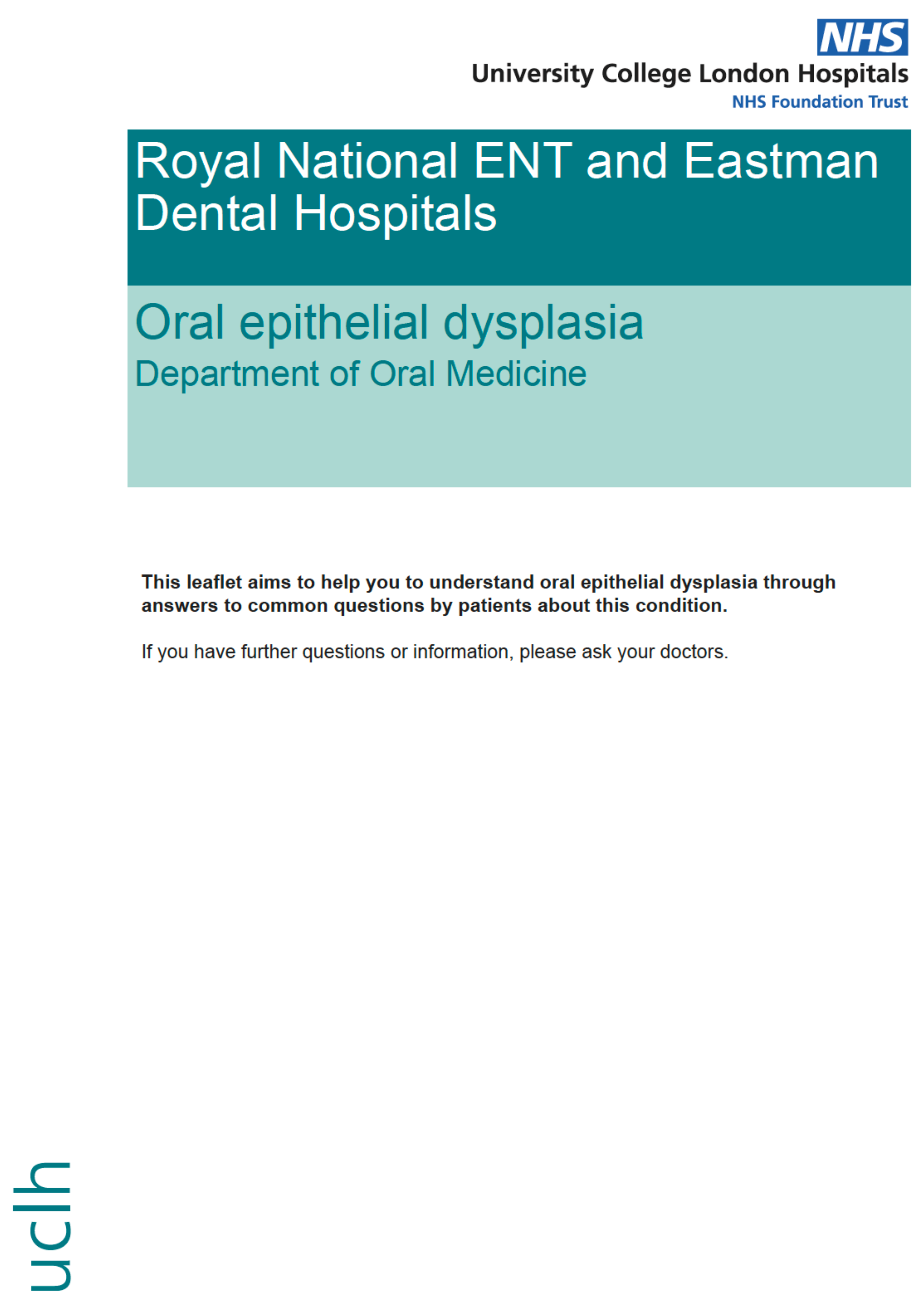
Do you have any other suggestions about how we could improve this leaflet?

Would you prefer the leaflet in:

Large Print? ☐ Audio? ☐ Easy Read ☐ British Sign Language DVD?

Braille? ☐ Another language ☐ (please state which one):

Appendix 13. The Patient Information Leaflet on Oral Epithelial Dysplasia



NHS
University College London Hospitals
NHS Foundation Trust

Royal National ENT and Eastman Dental Hospitals

Oral epithelial dysplasia

Department of Oral Medicine

This leaflet aims to help you to understand oral epithelial dysplasia through answers to common questions by patients about this condition.

If you have further questions or information, please ask your doctors.

What is oral epithelial dysplasia?

- This is when there are **abnormal cells** in the lining of your mouth.
- **It is not a mouth cancer.**
- It has the **possibility** of turning into **cancer**.
- It usually affects the tongue, floor of mouth, and/or gums. It can also affect the inside of the cheeks.
- It may affect 2 to 5 people per 100,000 of a population.
- It can affect **people of any age or gender.**
- Dysplasia **does not spread** to other parts of the mouth or body.
- It is **typically not infectious or inherited.**

Fig 1 Healthy mouth lining

What does oral epithelial dysplasia look like?

- **A red, white or mixed-colour patch** in the mouth lining that persists for more than a few weeks.
- It is **unlikely** to be **an ulcer** or **lump**.

What causes oral epithelial dysplasia?

- This risk is increased by habits such as **tobacco smoking or chewing and alcohol drinking.**
- Some mouth conditions such as **oral lichen planus** can increase the chance of dysplasia.
- **Human papilloma virus** may lead to the development of dysplasia or mouth cancer. This virus can be acquired by sexual encounters.

How do we diagnose Oral Epithelial Dysplasia?

- We need to **remove a small piece** of the lining of your mouth. This is called a biopsy.
- The **pathologist** will examine this and tell us if there is dysplasia and how bad it is (what the degree of dysplasia is).
- The **degree of dysplasia** is usually graded as **mild, moderate or severe**.
- Please ask for our Oral Mucosal Biopsy information leaflet for more information.

What are the risks for developing mouth cancer?

- It remains difficult to estimate the **personal risk** for a dysplasia to change to cancer.
- This risk is **low** in **mild dysplasia** and **high** in the **severe** dysplasia.

How do we treat oral epithelial dysplasia?

- Your specialist will suggest the treatment based on your **personal risk** and **dysplasia grade.**
- The treatment aims to prevent cancer developing in the mouth.
- We want **all dysplasia to be removed** whenever possible.
- We may not remove the areas with mild dysplasia but examine you periodically.
- Most moderate dysplasia and all severe dysplasia needs removal.
- Treatment usually requires **surgical removal** of the abnormal area.
- You will need **periodic follow-ups** with your dentist or us after treatment. This is to look for any further changes in the lining of your mouth.

How to manage the possible effects of the disease or treatment?

- You can speak to your dentist, doctor or dysplasia specialist for support and advice.
- You can speak to the GP if your diagnosis is affecting how you feel. You may search for the available mental health service around you: https://beta.nhs.uk/find-a-psychological-therapies-service/

What can you do?

- **Avoid smoking or chewing tobacco** - both are linked to dysplasia.
- **Limit alcohol intake** to as little as possible.
- **Visit** your dentist and/or specialist **regularly**. This is to identify any changes of your mouth lining.
- Ask for **help** from your dentist or doctor if you notice **unusual changes** in your mouth or lips. Examples include **a patch ulcer or a lump that lasts longer than 2 weeks**. This can be with or without pain.
- **Talk to your GP to talk for smoking / alcohol advice.** You can also look for web-based NHS services such as Smoke Free and Alcohol Support.
- **Avoid unsafe sex.** It may increase the chance of getting human papilloma virus.
- **Eat plenty of fruits and vegetables.** This may reduce the risk of dysplasia and mouth cancer.

How can you help other patients?

- Ask your doctors about research and clinical trials for dysplasia.
- You can find more information on the NHS Clinical Trials page: https://www.nhs.uk/conditions/clinical-trials/

Where can I get more information?

You can find further information about dysplasia or its related conditions on the web:

- British and Irish Society of Oral Medicine https://www.bisom.org.uk
- British Association of Dermatologists https://www.bad.org.uk

UCLH cannot accept responsibility for information provided by external organisations.

Contact

Department of Oral Medicine reception 020 3456 1061

If you need a large print, audio, braille, easy read, age-friendly or translated copy of the document, please contact us on:

Telephone: 020 3456 5076.

We will try our best to meet your needs.

PALS - If you have any concerns

PALS is a patient-friendly, easy to access service designed to provide a personal contact point to assist patients, relatives and carers. If you have a problem that you have not been able to sort out we can help you to resolve it.

The PALS office is located in the main atrium of University College Hospital, 235 Euston Road, London, NW1 2BU.

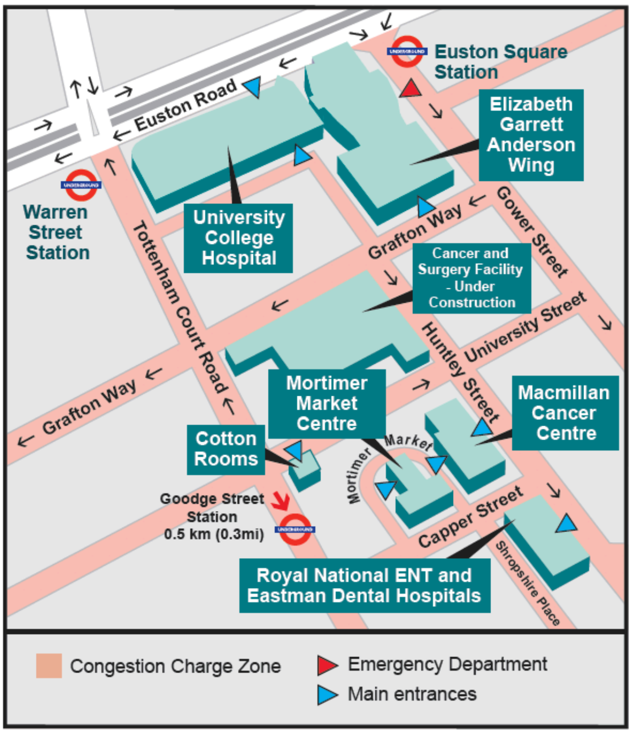
PALS are open:	Monday to Friday: 10:00 till 16:00
Telephone:	020 3447 3042
Email:	uclh.pals@nhs.net

How to find us

Royal National ENT and Eastman Dental Hospital

47-49 Huntley Street, London WC1E 6DG
www.uclh.nhs.uk

Huntley Street is close to Euston, Warren Street and Goodge Street Underground Stations and there are bus stops nearby. Apart from limited disabled parking there is no car parking at the hospital. You are advised to travel by public transport.



We are committed to delivering top-quality patient care, excellent education and world class research

Safety
Kindness
Teamwork
Improving

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