Information needs and oral epithelial dysplasia: development and psychometric evaluation of a novel instrument

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Abstract

Objectives

Oral epithelial dysplasia (OED) can lead to significant information needs (IN) related to the risk of cancer development, the need for long-term monitoring and potential intervention. The present study aimed to develop and perform preliminary psychometric testing for a novel IN instrument specific to OED.

Subjects and methods

Patients diagnosed with OED were invited to complete the Oral Epithelial Dysplasia Informational Needs Questionnaire (ODIN-Q), which was developed based on a known theoretical framework and with items generated via expert input and the literature. Face and content validity were initially assessed prior to finalisation of the tool. ODIN-Q was tested for internal consistency and test-retest reliability along with construct validity.

Results

ODIN-Q consists of 35 items, categorised under six domains, and rated by dual four-point Likert scales (amount of information received and degree of importance). Internal consistency (Cronbach's alpha) was rated 'excellent' for the scale (0.93) and both subscales (0.92/0.94). For test-retest reliability, moderate agreement was found (κ = 0.49-0.53). Regarding construct validity, a significant but limited relationship was found between ODIN-Q and the Krantz Health Opinion Survey.

Conclusion

ODIN-Q showed adequate psychometric properties of reliability and validity. Further validation is, however, needed to assess its structural validity and responsiveness.

Introduction

Oral epithelial dysplasia (OED) is an architectural and cytological abnormality of the oral epithelium characterised by an increased risk of oral cancer development (Mehanna, Rattay, Smith, & McConkey, 2009). It is considered a precursor of invasive oral squamous cell carcinoma, which is known to arise via sequential genetic and cytologic changes (Cho & Song, 2018). Oral epithelial dysplasia is diagnosed histologically, often in association with clinically evident abnormality of the oral mucosa including leukoplakia, erythroplakia, and oral lichen planus. Available literature suggests that approximately 12% of OED patients develop oral squamous cell carcinoma within a mean of 4.3 years from diagnosis, although the sub-group of individuals with severe OED is reported to develop oral cancer in up to 24% of the cases (Mehanna et al., 2009). A recent systematic review report an annual rate of oral cancer development of 1.7% and 3.5% for mild and severe OED, respectively (Iocca et al., 2020). Well-established risk factors include tobacco use, alcohol drinking and betel nut chewing (Iocca et al., 2020). In contrast, the pathogenetic role of other factors such as high-risk HPV types (e.g. HPV-16 and 18) is yet to be conclusively demonstrated in OED (Porter, Gueiros, Leao, & Fedele, 2018). Management of OED typically includes long-term surveillance, which can be lifelong (van der Waal, 2014) as well as surgery, although there remains little robust evidence regarding the efficacy of surgical resection in reducing the risk of oral cancer development (Mehanna et al., 2009).

Due to potential very long monitoring, the information provided to patient becomes a pivotal aspect of OED management. Previous research has suggested that insufficient information on health conditions can induce the fear of the unknown and uncertainty (Carleton, 2016) and, with respect to OED, this may be perceived as a barrier to seek oral cancer screening (Shepperd, Howell, & Logan, 2014). In contrast, information may in some instances lead to a cognitive overload for the patients, who may forget relevant information. Not all patients wish for all information (Christalle et al., 2019), which can be perceived as too alarmist and distressing, and cause anxiety (Waldron et al., 2011).

In general, appropriately informed patients experience reduced uncertainty than less informed patients that can, in turn, improve their compliance and satisfaction with treatment, ability to cope with the illness or adverse side effects of therapy and overall perception of the quality of care (Clarke et al., 2015; Neumann et al., 2011). Despite the pervasive use of the Internet, health care professionals (HCPs) remain the most reliable source of health-related information. The information available on the world wide web may be of poor quality, difficult to read or comprehend and lack actionability (Alsoghier, Ni Riordain, Fedele, & Porter, 2018). Nevertheless, there is often a gap between information needed by patients and that provided by their clinicians, and hence a risk of poor shared decision-making between the patient and HCPs (Rask, 2017; Weymann, Harter, & Dirmaier, 2016). Closing such a gap requires the delivery of tailored information based up on a patient's true needs and preferences (National Institute for Clinical Excellence, 2012; Neumann et al., 2011). One increasingly common method to do so is to acquire this information by using patient-reported experience measures (PREMs) such as information needs (IN) instruments (Christalle et al., 2019; Dall'Armi et al., 2013).

Information needs instruments can be useful to identify the individual's IN and therefore may serve as an educational source for tailored and relevant information (Christalle et al., 2019). Numerous IN generic and specific instruments available for different conditions with many of these instruments lacking reliability assessment and hypothesis testing and being rated as inadequate for content validity (Christalle et al., 2019). Of importance, none of these measures is known to accurately assess the sufficiency and importance of information given about OED. Information needs were previously evaluated in the context of oral precancerous lesions (Lin, Chen, Peng, & Chen, 2015) and oral cancer (Chen, Lai, Liao, Chang, & Lin, 2009). However, available studies used non-specific IN instruments (e.g. a cancer-generic instrument for oral cancer and precancerous conditions), therefore raising possible concern regarding their validity in this disease-specific group. The objectives of the present study are to develop the Oral Epithelial Dysplasia Informational Needs Questionnaire (ODIN-Q) and preliminary assess its psychometric properties - content and face validity, construct validity (hypothesis testing), test-retest reliability and internal consistency in a cohort of patients diagnosed with OED at a single UK site.

Methods

This was a prospective, observational questionnaire-based quantitative study conducted from October 2017 to December 2019. Ethical approvals were obtained from the Cork University Dental Hospital in Ireland [dated 26 October 2017] and the NHS Health

Research Authority, Research Ethics Committees [reference, 18/LO/1340] for the pilot and validation studies, respectively. The study was registered in https://clinicaltrials.gov [reference, NCT04153266]. Inclusion and exclusion criteria are presented in Table 1.

Development of ODIN-Q

The stress and coping theory (Lazarus & Folkman, 1984) guided the development of ODIN-Q. It suggests that dealing with stressful events [e.g. receiving a diagnosis with oral precancer] requires multiple behavioural and cognitive strategies to be adopted by individuals, including seeking information to understand the new health-related and possibly alarming event and its effect on well-being (Galloway et al., 1997; Lazarus & Folkman, 1984). This theory was considered suitable as a theoretical foundation for IN tools in patients with various health conditions (Galloway et al., 1997; Rask, 2017). The items for ODIN-Q were adapted and modified from the following IN instruments, as well as literature and clinicians' input (Pian, Song, & Zhang, 2019):

1) Reliable, valid and highly adopted IN instruments for patients with metastatic disease (Cassileth, Zupkis, Sutton-Smith, & March, 1980), breast cancer (Galloway et al., 1997; Luker et al., 1995) and prostate cancer (Dale, Jatsch, Hughes, Pearce, & Meystre, 2004).
2) The concerns reported in quantitative and qualitative studies of oral potentially malignant disorders (OPMDs) (Lin et al., 2015; Tadakamadla, Kumar, Lalloo, & Johnson, 2017), oral cancer or its symptoms (Allen & Farah, 2015) as well as non-oral cancer (Tariman, Doorenbos, Schepp, Singhal, & Berry, 2014) and precancerous conditions (Rask, 2017).
3) Input from Oral Medicine clinicians (RNR and SP) based on the expert opinion, available evidence and common concerns reported by patients in the daily clinical practice.

When considering the scale properties for ODIN-Q, the dual scale format adapted from Dale's IN instrument for prostate cancer (Dale et al., 2004) was considered appropriate as it assesses how sufficient was the information on an item (too much, enough, not enough, none) and whether it is important (very, yes, not very, not at all). The initial version included 56 questions which were not labelled under domains (Galloway et al., 1997) as agreed initially by the study team.

Qualitative assessment of ODIN-Q (content and face validity)

Expert review of ODIN-Q

The initial version of ODIN-Q (v 1.0) was reviewed by thirteen Oral Medicine experts to confirm its content validity. A checklist of four specific criteria [clarity, statement fit, redundancy and consistency] was followed to assess the content of ODIN-Q (Mastaglia, Toye, & Kristjanson, 2003). The majority of experts (84%) considered the items to be matching and asking about the same general topic. Nevertheless, around half of the experts noted some concerns regarding the clarity and redundancy of specific items, which indicated the need for further revisions (Figure 1). Examples of the received feedback from experts and performed actions are shown in Table 2. Experts have also recommended grouping the items under domains to maintain the reliability of responses and excluding unclear, irrelevant and redundant items which led to a reduction of items from 56 to 37.

Patient review of ODIN-Q

Face validity, which is an aspect of content validity, was determined by a sample of 5 patients attending Oral Medicine Clinics at Cork University Dental Hospital in Ireland. This sample included 3 males and 2 females patients with a mean age of 60 years (38-73 years).

At the time when the study was planned, there was no available method to assess or quantify the face validity (October 2017-April 2018). A Delphi study that provided standardised methods to assess the content and face validity was however published later to the assessment (Terwee et al., 2018). Thus, an evaluation form similar to that used for experts (Mastaglia et al., 2003) was modified to include questions concerning clarity [is the questionnaire clear?], relevance [is the questionnaire related to your condition?] and acceptability [in general, do you find the questionnaire acceptable?] (Moses, Wiggers, Nicholas, & Cockburn, 2005) rather than statement fit, redundancy and consistency. The participants requested to change questions with medical jargon, re-word and shorten specific questions and omitting two questions related to insurance and spiritual/religious support (Table 2). Further revisions improved the readability from the 6th grade level (Kincaid, Fishburne Jr, Rogers, & Chissom, 1975) in the initial version to the level between 4th and 5th grades in the later version of ODIN-Q (v 2.0). Both were measured by an online readability calculator (https://readable.com).

Validation study of ODIN-Q

The study investigator (AA) identified the potential participants among the patients attending their regular clinics and invited them to consider participation. Those who meet all the inclusion and none of the exclusion criteria were recruited and asked to complete the self-administered study questionnaires after their routine clinical visit or at home and return it by post. To determine the scale repeatability participants were asked to complete the ODIN-Q one week after their initial attempt and return the completed ones using the given pre-paid envelopes.

There are no standardised statistical methodological tests available to assess and validate an IN questionnaire. However, the recently developed checklists by the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) to determine the psychometric properties of PROMs were followed for ODIN-Q validation (Mokkink et al., 2019; Prinsen et al., 2018).

Internal consistency was measured through Cronbach's α, which was interpreted as excellent (>.90), good (>0.80), acceptable (>0.70), questionable (>0.60), poor (>0.50) and unacceptable (<0.50) (George & Mallery, 2003).

As participants were asked to complete the ODIN-Q again one week after their initial attempt, the consistency of both completions (test-retest reliability) was assessed using the weighted Cohen's kappa coefficient (κ) for ordinal scales (Sim & Wright, 2005). Although the interpretation for κ coefficients is commonly arbitrary, these were interpreted as almost perfect (0.81 or higher) substantial (0.80-0.61), moderate (0.60-0.41) and fair if at or below 0.40 (Landis & Koch, 1977).

Construct validity or hypothesis testing was assessed by comparisons between ODIN-Q and another instrument that measures a similar construct [convergent validity] (Mokkink et al., 2019). The sum scores of ODIN-Q subscales were matched to those of the Krantz Health Opinion Survey (KHOS) (Krantz, Baum, & Wideman, 1980). KHOS is one of the highly used and reliable instruments that has been used to assess the preference for information (KHOS-I, seven items) and active involvement in own health care decisions (KHOS-B, nine items). Shapiro-Wilk normality test indicated the skewed distribution of ODIN-Q scores ($P < .05$). Thus, the Spearman's rank correlation coefficient with a two-tailed test of significance was used to measure the magnitude of correlations between the scores of ODIN-Q and KHOS (Dinning & Crampton, 1989).

For sample size calculation, there is no present consensus to determine the sample size for the validation of a patient outcome measure (Anthoine, Moret, Regnault, Sébille, & Hardouin, 2014). However, the COSMIN checklist for study design of PROMs suggests that sample size, based on general guidance (Prinsen et al., 2018), can be excellent (≥100 participants), good (99-50), fair (49-30), or poor (<30).

Data analysis and quality control

Responses to ODIN-Q were recorded using Microsoft Excel proforma (version 16.29.1) and imported to the IBM Statistical Package for Social Sciences (SPSS) software (version 22.0) for statistical analyses. Questionnaires with non-responses of ≥%10 for each subscale of ODIN-Q were omitted whereas those of less were matched to the average answer of each item (Downey & King, 1998).

Results

Following the assessments by experts and patients, the revised version of ODIN-Q (v 3.0) included 35 questions about IN that was represented under six domains (general information, investigative tests, treatments, physical aspects, psychosocial aspects and the medical system and access to information). Other questions on the preferred sources of information, ranking of HCPs – if one-to-one is selected and the open-ended question at the end of ODIN-Q were maintained for this version. Steps performed from identifying the potentially eligible patients to recruitment are highlighted in Figure 2.

The 86 participants were 41 males and 45 females. 78% of them were White and the remaining 22% of Asians, Black or mixed ethnicity. The mean and median age was at 65 years (31-89 years). Based on WHO grading for OED (El-Naggar, Chan, Grandis, Takata, & Slootweg, 2017), 63% of participants had the diagnosis of mild and mild to moderate grades, 19% of moderate and 18% of moderate to severe and severe dysplasia.

Psychometric properties of ODIN-Q

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 (α = 0.92) and degree of importance subscales (α = 0.94) and for the overall scale of ODIN-Q (α = 0.93). The analyses of domains under each subscale demonstrated that most domains had good (>80) or acceptable consistency (>.70). Exceptions were seen with investigative tests and psychosocial aspects domains under both subscales, which showed questionable (>.60) to poor consistency (>.50). However, both domains showed higher scores when one item was removed from the analyses of former and latter domains, respectively (Table 3). Also, the Spearman's test indicated no statistically significance [*p* > .05] and/or low inter-item correlations [*r* < 0.40] (Guilford, 1950) between these two items and other items under the first subscale.

Test-retest reliability

The analyses of agreement between the first and second completions by 52 out of the 86 participants, who returned the 2nd-week questionnaires by mail, indicated moderate agreements for both subscales: the amount of information received (κ = 0.53) and the degree of importance (κ = 0.49). Similarly, the agreements on all domains under both subscales were rated as moderate; 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 of most items indicated substantial to moderate agreements with few others, however, demonstrated fair agreements (Table 4).

Validity

Construct validity (Hypothesis 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 limited (Guilford, 1950). In contrast, higher levels of correlation were found when KHOS subscales and scale when compared to each other (Table 5).

The final version of ODIN-Q after the validation study

Two items [‘*the genetic testing and chance of inheritance to children’* and ‘*how the disease/treatment affects the job/career’*] were omitted from the final version based on the reliability analyses and relevance to the clinical care of patients with OED. The characteristics and content of the 33-item ODIN-Q (v 3.0) are shown in Supplementary file 1.

Discussion

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 (Grilo, dos Santos, Gomes, & Rita, 2017; Lin et al., 2015), such as perhaps OED. Also, providing reliable information to dental patients could optimise the awareness of their disease (Ali, Woodmason, & Patel, 2014) and improve the early detection of new OED lesions or possibly the malignant transformation of existing lesions. This is illustrated by the locus of control (LOC) theory (Rotter, 1966) which is constituted by two loci. The internal LOC reflects the individual belief in self-control over his/her health. In contrast, external LOC demonstrates the belief in health control or influence by factors that cannot be controlled by the individual (Rotter, 1966; Syx, 2008). Of note, higher control over health outcomes is likely to be found among those who have their beliefs driven by the internal LOC when communicated with health information (Krantz et al., 1980; Syx, 2008).

The development and validation of the present ODIN-Q was performed by teaming up patients and clinical experts to maintain essential aspects of methodological quality that ensure adequate reliability and validity to identify the needs and priorities of patient information about OED. Similar to two studies on the breast (Chalmers, Luker, Leinster, Ellis, & Booth, 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 essential to the respondent despite their answer in the first subscale. Other instruments were limited for assessing either of these subscales, such as degree of importance (Dall'Armi et al., 2013; Galloway et al., 1997) or presented different responses for each item (Hyland, Jones, & Hanney, 2006).

The present ODIN-Q demonstrated adequate validity with its overall content been reviewed and revised by experts who mainly agreed on its relevance and acceptability. To improve the efficiency of the ODIN-Q, resolving concerns related to its clarity and redundancy led to a reduction in the number of items from 56 to 37 and 35 and 33 items following the experts and patients reviews and the validation study, respectively. Similar to these findings, the assessments of content and face validity of other patient’s needs instruments helped to eliminate unnecessary items concerning prostate cancer (Dale et al., 2004) and to change the format of specific others related to the cancer needs of young individuals (Clinton-McHarg, Carey, Sanson-Fisher, D'Este, & Shakeshaft, 2012). Although instruments must be readable by the targeted population especially individuals with less education (Bonevski et al., 2000; Clinton-McHarg et al., 2012), assessing the readability levels of IN tools is frequently overlooked. ODIN-Q maintained the recommended readability level of 4th to 5th US grade level, which was slightly lower than the initially reported level of generic cancer needs instrument [6th grade level] (Clinton-McHarg et al., 2012).

Another aspect of validity, hypotheses testing, was determined by assessing the relationship of ODIN-Q with an instrument with adequate psychometric properties and measuring similar construct (desire for information) (de Vet, Terwee, Mokkink, & Knol, 2011; Mokkink et al., 2019). Within the limitation of the relationship, the present findings indicated that respondents who had their IN sufficiently met were those who have a higher preference for information. These findings are perhaps explained by the commonly adopted and ODIN-Q-based hypothesis of stress, appraisal and coping theory (Lazarus & Folkman, 1984) 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 (Rutten, Arora, Bakos, Aziz, & Rowland, 2005; White & Gallagher, 2010). As a consequence, these participants will have sufficient information and met IN compared with their passive counterparts, as reported with a study that investigated these behaviours using KHOS in 260 patients undergoing oral biopsy in Spain (Lopez-Jornet, Camacho-Alonso, & Sanchez-Siles, 2012).

Overall, the ODIN-Q 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. This is comparable to the instruments that were mainly used to develop ODIN-Q: TINQ-BC (0.96) and Dale's IN instrument for prostate cancer (0.91) (Dale et al., 2004; Galloway et al., 1997). Assessments of test-retest reliability using weighted κ demonstrated overall moderate agreements for both ODIN-Q subscales with less variation of scores between items (κ = 0.20-0.76) compared to the Cancer Needs Questionnaire (κ = 0.09-0.94) (Clinton-McHarg et al., 2012), and somewhat similar to the unweighted κ values reported with the Systemic Lupus Erythematosus Needs Questionnaire (κ = 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 (Ghisi, Grace, Thomas, Evans, & Oh, 2013) or lack of evidence on test-retest reliability (Alamanou, Balokas, Fotos, Patiraki, & Brokalaki, 2016; Dale et al., 2004).

The present study was limited by the lack of assessments of fundamental psychometric properties such as criterion validity (Mokkink et al., 2019). Furthermore, responsiveness was not presently assessed as the study did not principally aim to detect the overtime changes of IN. Although a sample of 86 participants is considered adequate to evaluate the internal consistency (Mokkink et al., 2019), further validation is needed to demonstrate acceptable level for consistency (>0.70) for investigative tests and psychosocial aspects domains which were initially below this level. Also, a minimum of five respondents for each item is recommended for the factor analysis (Comrey, 1992). As the ODIN-Q was developed based on a sound theoretical framework that has been used in other information needs questionnaire, the exploratory factor analysis was not necessary.

Due to the relatively low incidence rate of OED, further research may consider multi-centre recruitment to uphold an adequate sample needed to perform the confirmatory factor analysis (structural validity) and field-testing of ODIN-Q, which will provide further evidence on its reflection of the patient's IN (de Vet et al., 2011; Nankivell, Dunn, Langman, & Mehanna, 2012; Prinsen et al., 2018). Cross-cultural validation will also be needed for its application in patients with a specific disease (e.g. patients diagnosed with oral lichen planus), ethnicity (e.g. minority groups), age-group (e.g. young individuals), health care setting (e.g. primary care) in addition to other languages and countries. Furthermore, longitudinal IN assessments using ODIN-Q would enable to evaluate the changes of IN overtime as well as before and after implementing educational interventions (responsiveness) (de Vet et al., 2011).

Conclusion

A questionnaire was developed to determine what information is needed and how important it is for patients with OED. The assessment of the psychometric properties of this questionnaire (ODIN-Q) with 86 patients demonstrated its excellent internal consistency and moderate agreements between first- and second-week completions. Also, the construct validity was reflected with a significant but limited relationship between ODIN-Q and another instrument of similar construct. Further longitudinal and perhaps a cross-cultural assessment of ODIN-Q is however needed with an adequate cohort of patients with OED to determine its structural validity and responsiveness to confirm its accurate reflection of the respondent's information needs.

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Figure 1 Visual representations of the experts' responses to the content assessment (n=13).

Figure 2 Steps performed to identify and recruit potentially eligible patients.

Table 1 Inclusion and exclusion criteria for the study.

Inclusion Criteria

1. Adults aged 18 or above at the time of the screening visit and subjective disclosure of good command of English language both written and spoken.
2. Being able to consent.
3. Diagnosed with OED as per current standard diagnostic criteria (El-Naggar et al., 2017).
4. 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 and to understand the diagnosis of OED.
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).

Table 2 Examples of the feedback from experts and patients and performed actions for ODIN-Q (version 1.0)

Criteria	**Comment/s**	**Action taken**
	Oral Medicine experts	
Clarity	*Not sure what is meant by "fear of recurrence or progression to cancer" (expert 05)*	'*Fear of recurrence'* was omitted as it is more likely to suit cancer than OED
	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 (expert 06)	The items were revised grammatically by the core study team (AA, RNR and SRP)
	"Clinical features" is an expression that probably means nothing for someone without medical background (expert 08)	The question '*what are the clinical features of OED?'* was replaced by '*how it looks inside the mouth?'*
	Some questions contain jargon which may not be understood by patients… (e.g. clinical features) (expert 12)	
	"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? (expert 10)	The subscale title '*degree of importance*' was replaced by '*is this item important to you?*'

	'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 (expert 10)	This item was replaced by 'what is likely to happen to OED in the future' and moved to the end of '*information about the disease*' domain (Q10)
Statement fit	*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 (expert 08)*	The ODIN-Q was subsequently reviewed by five patients
Redundancy	*I wonder if all patients will feel able to complete because of there being so many to answer (expert 06)*	Twenty-one unnecessary items were eliminated
	I think that it is too long to keep a patient attentive (expert 07)	
	This is a huge number of questions (expert 11)	
	Patients	
Clarity	*I understand "cognitive" but I'm not sure other people will*	The question '*how to deal with the emotional and cognitive disturbances?'* was replaced with *'how to cope with the possible effects of the disease/treatment?*'
	Wording is weird in the "why and why not the OED is	The item was changed to '*what will happen if it is not*

	being treated?"	*treated?*'
Relevance	*Not applicable for job and career please as some of us are retired*	The following was added to the question; '*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 as the validation study was conducted in the NHS hospitals
	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
	Not much point in getting information about screening when I have it already	None as ODIN-Q was aimed for use despite the stage of the disease and treatment
	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	
Acceptability	*This is too long*	Further two items were removed, and others underwent further reduction of words and syllables to improve readability
	Don't think it is acceptable to discuss spiritual and religious things with the doctor	The item about spiritual/religious support was omitted

Table 3 Internal consistency (Cronbach's α) 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.

Table 4 Reliability coefficients (test-retest) of the ODIN-Q.

ODIN-Q item	**Weighted Kappa's coefficient (κ)**	
	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 aspects		
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 aspects		

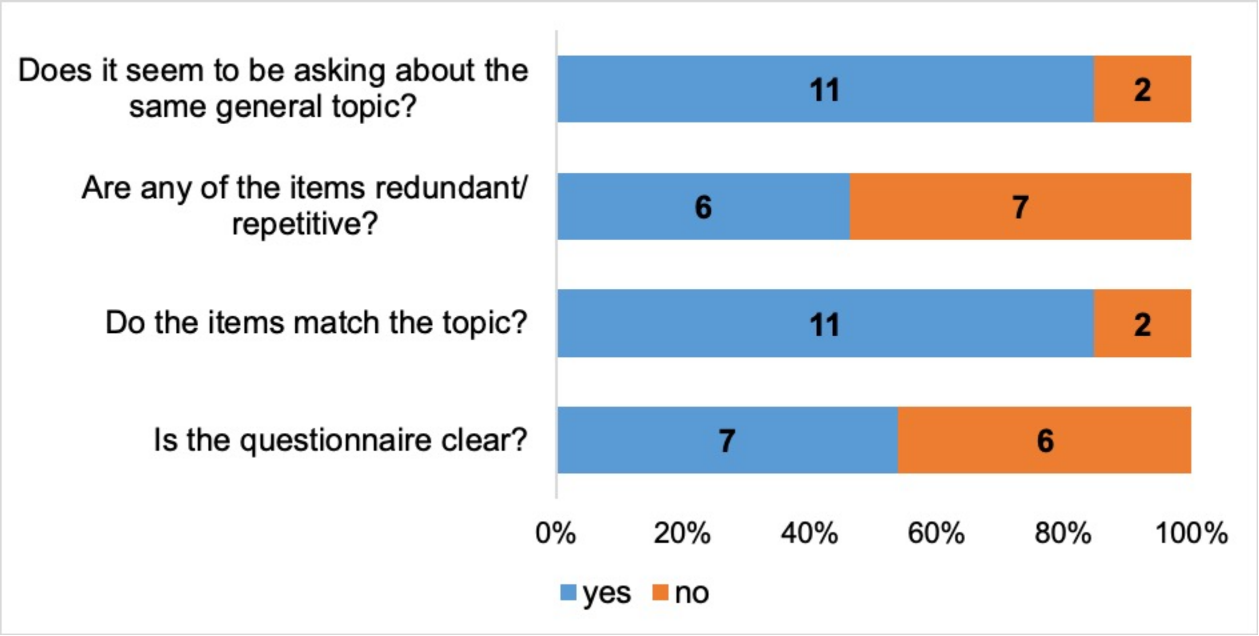
Fear of progression to cancer.	0.66	0.20
Coping with the possible effects of the disease/treatment.	0.65	0.42
How the disease/treatment affects social life.	0.60	0.51
How the disease/treatment affects job/career.	0.50	0.59
Medical system and access to information		
The experience of the doctor and other 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

Table 5 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).



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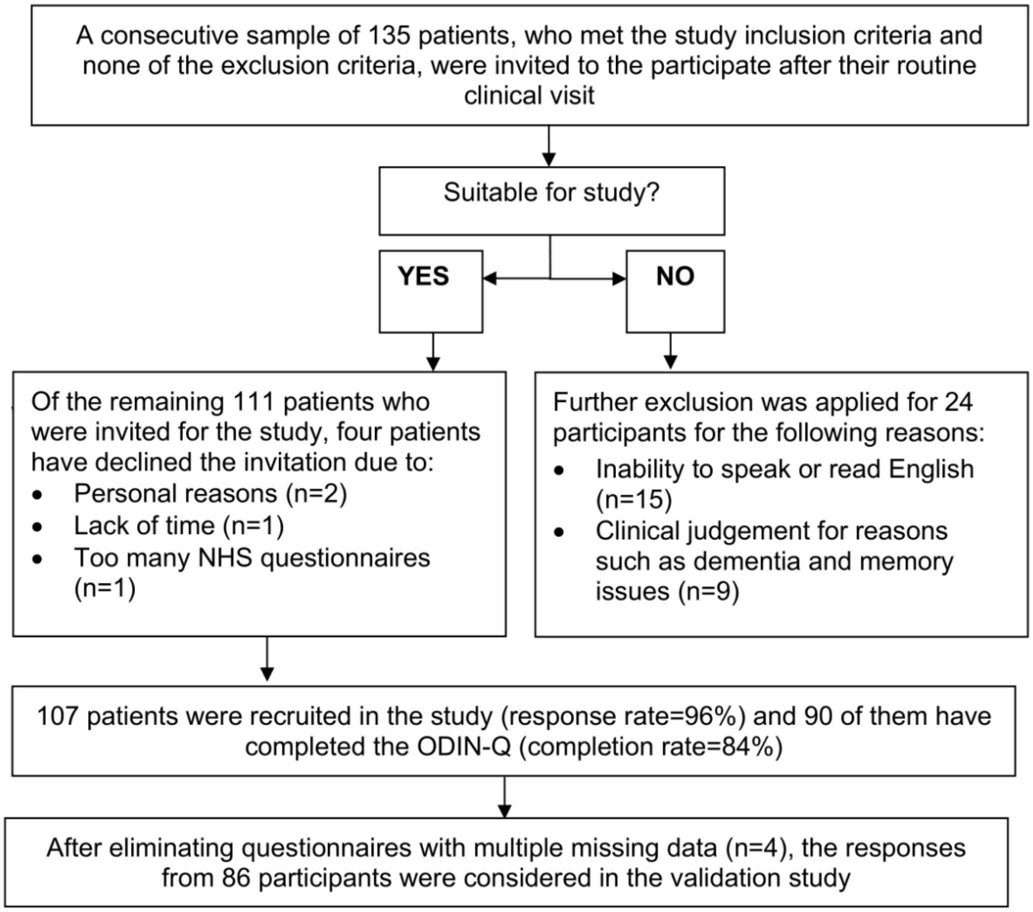

A consecutive sample of 135 patients, who met the study inclusion criteria and none of the exclusion criteria, were invited to the participate after their routine clinical visit

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 was applied for 24 participants for the following reasons:

- Inability to speak or read English (n=15)
- Clinical judgement for reasons such as dementia and memory issues (n=9)

107 patients were recruited in the study (response rate=96%) and 90 of them have completed the ODIN-Q (completion rate=84%)

After eliminating questionnaires with multiple missing data (n=4), the responses from 86 participants were considered in the validation study

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