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World Workshop on Oral Medicine VIII: Development of a Core Outcome Set for Dry Mouth: A Systematic Review of Outcome Domains for Xerostomia.

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ABSTRACT

Objective: The purpose of this study was to identify all outcome domains utilized in clinical studies of xerostomia, i.e. subjective sensation of dry mouth. This study is part of the extended project 'World Workshop on Oral Medicine Outcomes Initiative for the Direction of Research (WONDER)' to develop a core outcome set (COS) for dry mouth.

Study design: A systematic review was performed on MEDLINE, EMBASE, CINAHL and Cochrane Central Register of Controlled Trials databases. All clinical and observational studies that assessed xerostomia in human subjects from 2001 to 2021 were included. Information on outcome domains was extracted and mapped to the Core Outcome Measures in Effectiveness Trials (COMET) taxonomy. Corresponding outcome measures were summarized.

Results: From a total of 34,922 records retrieved, 688 articles involving 122,151 persons with xerostomia were included. There were 16 unique outcome domains and 166 outcome measures extracted. None of these domains or measures was consistently utilized across all the studies. Severity of xerostomia and physical functioning were the two most frequently assessed domains.

Conclusion: There is considerable heterogeneity in outcome domains and measures reported in clinical studies of xerostomia. This highlights the need for harmonization of dry mouth assessment in order to enhance comparability across studies and facilitate synthesis of robust evidence for the management of patients with xerostomia.

Key words: Dry mouth, xerostomia, salivary gland hypofunction, hyposalivation, outcome domains, outcome measures

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INTRODUCTION

Dry mouth is a common condition that can significantly impair oral health, daily oral functioning, quality of life, as well as increase the economic burden associated with health care services^{1,2}. Previous clinical studies reported that the proportion of individuals with dry mouth in the population ranged from 5.5% to 46%³. As the population ages, the prevalence of dry mouth is likely to increase, yet the condition appears to remain underrecognized and undertreated^{1,4}.

Dry mouth is usually referred to as xerostomia, salivary gland hypofunction or hyposalivation. These terms are used interchangeably by clinicians, researchers, and patients, although they convey a different meaning. Xerostomia is self-reported subjective feeling of oral dryness. Salivary gland hypofunction is objectively measured low saliva secretion, i.e. below normal secretion. while hyposalivation is a diagnosis when saliva secretion becomes pathologically low (i.e. low unstimulated whole saliva flow rate of ≤ 0.1 mL/min and/or a stimulated whole saliva flow rate of ≤ 0.5 – 0.7 mL/min)⁵. The exact nature of the relationship between xerostomia and salivary gland hypofunction are shown to be inconsistent, and people complaining of xerostomia frequently do not show objective signs of salivary gland hypofunction suggesting their symptoms may be secondary to change in the saliva composition^{6,7}. Similarly, patients with salivary gland hypofunction might not report xerostomia, as shown in a previous report which found that salivary gland hypofunction and xerostomia coincided in only one-sixth of those with either condition⁸.

Dry mouth has several causes which often overlap or interact. It can be primarily induced by several classes of medications (e.g., antidepressants, antipsychotics, bronchodilators, decongestants, benzodiazepines, antihistamines, among many others), which are by far the most common contributing factors for chronic dry mouth⁹. Independent of the class of medication being taken, polypharmacy on its own (which is very common in elderly patients) also increases the likelihood of developing dry mouth¹⁰. Dry mouth often occurs following

radiation therapy to the head and neck. Other conditions such as Sjögren's syndrome (also known as Sjögren's disease), diabetes mellitus, eating disorders, dehydration, and mental illnesses, as well as normal ageing can also cause a dry mouth ^{11,12}.

Treatment options for dry mouth should be based on the underlying condition or causative factors of each affected individual. Different therapeutic strategies for dry mouth can be broadly categorized into three domains comprising palliation, stimulation and regeneration. Palliative treatment includes water and a myriad of salivary substitutes such as oral lubricating gel, mouthwashes and artificial saliva ¹³. Various local and systemic strategies have been used to stimulate salivary secretion including topical salivary stimulants ¹⁴, pilocarpine ¹⁵, cevimeline ¹⁶, acupuncture ¹⁷, and electrostimulation ¹⁸. More recently, promising treatment strategies have been introduced for dry mouth in certain conditions which aim at the regeneration and recovery of salivary gland function, including gene therapy ¹⁹, stem cell replacement therapy ²⁰, B-cell depletion ²¹, and inhibition of co-stimulation of T cells ²². Although multiple studies have evaluated these interventions, it is difficult to compare their findings and draw conclusions, due to the lack of definition in the treatment outcomes and outcome measures. It is necessary then to determine the minimal set of outcomes to evaluate the effectiveness of the different interventions, in order to draw future conclusions about which treatment(s) are most effective for this condition.

A core outcome set (COS) is defined as an agreed minimum of outcome domains to be measured and reported in all trials of a particular treatment or condition ²³. There are three fundamental steps in the development of a COS: 1) identifying existing knowledge, 2) patient involvement and 3) the consensus process ²⁴. To date, no COS for the evaluation of interventions in clinical trials on dry mouth has been developed. This study is part of the extended project 'World Workshop on Oral Medicine Outcomes Initiative for the Direction of Research) (WONDER)' to develop a COS for clinical trials assessing the effectiveness of interventions for dry mouth. Each of the steps of the development of COS from the WONDER

project will be subsequently reported. For the first step, as dry mouth has both subjective (xerostomia) and objective (hyposalivation) components, for which a large number of outcome domains and measures exists, we decided to perform two independent systematic reviews to facilitate the identification and analysis of the existing knowledge. Accordingly, the aim of this study was to identify and describe all the outcome domains that are measured in studies assessing xerostomia, i.e. the subjective complaints of dry mouth.

METHODS

Registration and protocol

This systematic review was conducted according to the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA 2020 statement) ²⁵. The protocol was peer-reviewed and registered at PROSPERO under number register: CRD42021279791 (available at: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021279791).

Inclusion and exclusion criteria

We defined inclusion criteria for literature search and questions using the Population, Intervention, Control, Outcome, and Study Design (PICOS): P – humans with a dry mouth; I – any active preventive, palliative, or curative pharmacological or non-pharmacological treatment/intervention for dry mouth administered topically or systemically; C – no restrictions to the comparison; O – all dry mouth-related outcomes (objectively and subjectively measured); S – clinical trials (randomized and non-randomized) and observational studies (descriptive, cross-sectional, cohort, case-control).

All clinical and observational studies published in the literature that investigated the management of dry mouth in humans were included. The present systematic review included studies, which clearly reported at least one xerostomia or xerostomia-related outcome and/or outcome measure in the methods section. There was no limitation on the nature of samples

(e.g. convenience samples, population-based samples), type of interventions (e.g., pharmacological, surgical, lifestyle modifications, psychosocial), or the aspects explored (patient-reported, clinician-reported). Secondary analysis studies or studies that used the same population as the initial population were included; however, duplicate outcomes were described only once.

Excluded from the study were: (1) conference abstracts; (2) proceedings; (3) commentaries; (4) editorials; (5) protocols; (6) case reports; (7) case series with less than ten participants; (8) animal or laboratory studies; and (9) non-English language records. We also excluded studies where full text was not available.

Information sources and search strategy

The search strategy was developed in collaboration with an experienced bioinformation specialist (Drs. SvdW) according to the syntax rules of each database. On 15 September 2021, a systematic search of the scientific literature was performed for articles published from January 2000 through September 2021 in the following bibliographic databases: MEDLINE (PubMed), EMBASE (Ovid), CINAHL (EBSCO), and Cochrane Central Register of Controlled Trials (CENTRAL). The reproducible search strategies for all databases are available at Supplementary Table 1.

Selection process

Following the literature search, records from each database were exported into EndNote reference manager software (EndNote X7, Thomson Reuters, Philadelphia, PA, USA) and the duplicate articles were removed. Reviewer calibration was performed in two sessions on articles not included on this study prior to the initiation of the screening process. The Cohen's Kappa was 0.7 with a percentage of agreement of 85 between the various observers. In the first phase, the study group (AV, KD, RNR, VS, ARSS, MKS, PW, MLS, SN) screened the titles and abstract for relevance independently. In the second phase, five reviewers (ARSS, MKS,

PW, MLS, SN) performed full-text review for the retained articles. Reasons for exclusion were not recorded for all due to the high number of studies (n=2700). Any disagreement at both levels was resolved following discussion with the section heads (AV and KD). Searches were re-run before the final analysis, and any additional studies identified were retrieved for assessment.

Data items and collection process

Reviewers (ARSS and MKS) and assistant reviewers (PW, SN and MLS) extracted the following data: (1) author; (2) year of publication; (3) country; (4) type of study; (5) number of participants with a dry mouth; (6) mean, median, standard deviation and/or age range; (7) percentage of female persons with a dry mouth; (8) disease associated with a dry mouth; (9) subjective (xerostomia) or objective (salivary gland hypofunction) outcome recorded; and (10) level of outcome measurement (dichotomous, categorical, numerical/continuous or unclear). All data were extracted and described in a spreadsheet (Office Excel 2016; Microsoft Corp, One Microsoft Way Redmond, Washington, U.S.A).

Effect measures

Primary xerostomia-related outcome domains were summarized using all the assessment methods applied across included studies. We also summarized the variability in the utilization of all subjective outcome measurements.

Synthesis methods

A qualitative analysis and not a quantitative synthesis was considered because several different study designs were included, leading to potential heterogeneities across treatment interventions and outcomes reported in the xerostomia field. The findings of this review were presented in a table format along with a narrative summary of the outcome domains and respective measures.

RESULTS

Study selection

The systematic search initially retrieved 34,922 records. After removal of duplicates and screening of titles and abstracts, a total of 2,700 potentially relevant articles were identified for full-text eligibility screening. At the end of the screening process, 688 studies were included for xerostomia outcome domain extraction. Figure 1 visualizes the study selection process based on the PRISMA flowchart.

Characteristics of the included studies

The study characteristics are outlined in Table 1. Nearly three times more studies were published from year 2011 onwards than those between 2001 to 2010. The studies included a total of 122,151 persons with xerostomia, with a large variation in sample size across studies (10 to 64,947 persons). The median age of study participants ranged from 33 years to 69 years. There was heterogeneity in gender distribution among the included studies, with the proportion of female persons in mixed-gender studies ranging from 8% to 97%. Thirty and seven xerostomia studies exclusively enrolled female and male persons, respectively.

Over one-third of the studies originated from Europe (259/688; 37.6%), followed by Asia (218/688; 31.7%) and North America (131/688; 19.0%). The majority of included studies were cohort studies, followed by cross-sectional studies and randomized controlled trials (RCTs). As for studied conditions related to xerostomia, the greatest proportion of studies evaluated radiotherapy-induced xerostomia (RIX; 35.5%) and Sjögren's syndrome (14.2%). Of the included studies, 380 assessed outcomes of both xerostomia and salivary gland hypofunction while the remaining studies reported xerostomia outcomes alone (Table 1).

Outcome domains assessing xerostomia

In total, there were 166 individual outcome measures, which were reviewed and categorized into 16 unique outcome domains mapped according to the Core Outcome Measures in Effectiveness Trials (COMET) taxonomy²⁶ (outlined in Table 2).

Severity of xerostomia was the most frequently applied xerostomia outcome domain, measured in over two-thirds (482/688, 70.1%) of the included studies, followed by physical functioning (260/688, 37.8%) and presence of xerostomia (163/688, 23.7%). The number of studies assessing different outcome domains of xerostomia are depicted in Figure 2.

The following section outlines the details of each outcome domains and respective outcome measures based on the core area and modes of administration of the outcome measures.

A. Xerostomia core area (COMET core area 8 – gastrointestinal outcomes)

The present review extracted seven distinct outcome domains measuring different aspects of xerostomia, which include presence, severity, affect, frequency, duration, fluctuation and location of xerostomia. The lists of patient-reported outcome measures, and investigator-graded outcome measures assessing each specific outcome domain in this core area are present in Table 3 and Table 4, respectively.

1. Presence of xerostomia

Presence of xerostomia is typically measured using single questions with binary response (yes or no) by patients (Table 3). Of 118 studies assessing presence of xerostomia, 46 (39.0%) did not provide clear description of how the outcome was measured in the method sections. For studies on Sjögren's syndrome, the standard question "*Have you had a daily feeling of dry mouth for more than 3 months?*" was used in 40 studies for assessing presence of subjective oral dryness based on the 2002 American-European Consensus Group (AECG) classification criteria for Sjögren's syndrome²⁷ and the 2016 American College of Rheumatology/European League Against Rheumatism (ACR-EULAR) Classification Criteria for primary Sjögren's

syndrome²⁸. The most commonly used single question to assess the presence of xerostomia in the non-Sjögren's syndrome literature was the question "*Does your mouth usually feel dry?*" (11 studies). The wordings of other single questions are inconsistent across the literature, particularly with variation in the use of xerostomia symptom descriptors (oral dryness sensation, little amount of saliva) and in their time period (2 weeks, 3 months and 6 months).

2. Severity of xerostomia

The 'severity' domain encompasses the degree of subjective *patient-reported* symptoms related to xerostomia (Table 3; 362 studies), including sensation of oral dryness or discomfort, and *investigator-graded* severity of dry mouth (Table 4; 120 studies), which incorporates the assessment of both subjective symptoms and objective clinical signs and assessment of dry mouth.

Patient-reported severity of xerostomia were rated using a variety of response options, ranging from categorical verbal rating scale (VRS) and numerical rating scale (NRS) to visual analog scale (VAS). The 100-mm VAS-xerostomia was the most predominantly adopted scale for measuring severity of xerostomia, dominating in over a quarter (94/362; 26%) of the studies reporting patient-rated severity of xerostomia. In Sjögren's syndrome studies, the 0-10 dryness domain of the EULAR Sjogren's Syndrome Patient Reported Index (ESSPRI)²⁹ was used in 33 studies. The 11-point (0-10) NRS-xerostomia was applied in 18 studies. As for the categorical VRS, there was variation in the response categories, with both three or four response categories being the most commonly adopted measurement options (each used in six studies; usually with (no/mild/moderate/severe word choices).

There is a number of established investigator-graded criteria for the assessment of both xerostomia and hyposalivation as listed in Table 4. The Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer (RTOG/EORTC) radiation morbidity scoring scheme for salivary gland toxicity was most frequently applied for

assessing acute and RIX, and used in 71 studies (8 acute radiation morbidity; 41 late radiation morbidity; 22 both acute and late). Aside from the RTOG/EORTC, the Common Terminology Criteria for Adverse Events (CTCAE) radiation morbidity grading scale (41 studies) and the Late Effects in Normal Tissue-Subjective, Objective, Management and Analytical (LENT-SOMA) systems (6 studies) were also commonly used in studies assessing severity of xerostomia as side effect of radiotherapy (Table 3).

3. Affect of xerostomia

While severity of xerostomia reflects the sensory component of the symptoms, affect of xerostomia concerns immediate affective responses related to xerostomia. In other words, how unpleasant or disturbing xerostomia feels in affected individuals. This domain was less frequently explored in the literature than other xerostomia domains. The main instrument capturing the affect of xerostomia was the 1-item Bother Index (BI-1)³⁰. The BI-1 assesses “*how much of your dry mouth problem is bothering you?*” on an 11-point (0-10) scale, and has been applied in three studies. Other outcome measures of xerostomia affect were assessed with various ad hoc questionnaires across the studies (Table 3).

4. Frequency of xerostomia

Frequency of xerostomia is typically evaluated by a well-established standard question “*How often does your mouth feel dry?*”, with the response options of: never, occasionally, frequently and always. This question was used in 20 studies in this review (Table 3). This standard question has been used not only to assess the frequency of xerostomia, but also, after dichotomising, to determine xerostomia prevalence – especially for national survey estimates^{1,31}. In addition, the question itself has also been recommended to validate other self-reported instruments including the Xerostomia Inventory (XI)³².

5. Duration of xerostomia

Duration of xerostomia refers to time since the onset of xerostomia, and this has been recorded inconsistently in the literature. Three studies reported the duration of xerostomia based on the a patient interview, and one study used a non-standardized question “*Since when have you experienced dryness in the mouth?*” with arbitrary response categories of recently, several months, several years, and 10 years or more (Table 3).

6. *Fluctuation of xerostomia*

Fluctuation of xerostomia reflects a temporal pattern or variability in the presence and absence of xerostomia, together with changes in its intensity over different periods of time or daily activities. Difference in fluctuation of xerostomia can reflect both physiological and pathological changes in both unstimulated and stimulated saliva production. Periods of the day that are frequently assessed in the present review were during the night (seven studies), during daytime (six studies), while eating (three studies) and upon waking (three studies). There appears to be no standardized unidimensional scale assessing this aspect of xerostomia, and various types of single questions with binary, 4-point and 5-point categorical responses have been used in the literature (Table 3).

7. *Location of xerostomia*

There is no unidimensional outcome measure specific to the location of xerostomia.

B. Life impact core area (COMET core area 25, 26, 28, 30, 32)

There are five major life impact core areas covering eight different outcome domains for the assessment of xerostomia. These outcome domains include physical functioning, social functioning, psychological functioning, impact on oral health, xerostomia-specific quality of life, oral health-related quality of life, and general health-related quality of life. The lists of patient-reported outcome measures in each specific domain in this core area are summarized in Table 5.

1. Physical functioning (COMET core area 25 – physical functioning)

The physical functioning domain includes the abilities or difficulties in performing daily physical functioning including chewing, swallowing, speaking, as well as coping behavior related to xerostomia (e.g. need to sip liquids to aid swallowing). The most frequently assessed dimension of physical functioning related to xerostomia was the ability/difficulty to swallow (16 studies), followed by the ability/difficulty to speak (ten studies), the ability/difficulty to chew/eat (nine studies) and need to drink liquids to aid swallowing (six studies). The majority of studies assessed aspects of physical functioning with the use of single dichotomous questions (ten studies), followed by the VAS (nine studies) (Table 5).

2. Social functioning (*COMET core area 26 – social functioning*)

Only three studies assessed social functioning as distinct outcomes. Two studies used the patient interviews to elicit information on social functioning, while one study applied three yes/no questions asking if patients avoided speaking to people, stayed at home more or visited people less frequently due to dry mouth (Table 5).

3. Psychological functioning (*COMET core area 28 – emotional functioning/well-being*)

The psychological functioning domain includes changes in emotional functioning and sleep disturbance related to xerostomia. The Hospital Anxiety and Depression Scale (HADS) was used for the evaluation of both anxiety and depression of patients in three studies. Three studies evaluated different dimensions of sleep disturbance, including ability of sleep at night, difficulty in initiating sleep due to xerostomia, and the number of night waking episodes due to xerostomia (Table 5).

4. Impact on oral health (*COMET core area 30 – global quality of life*)

Eleven studies assessed different dimensions of impact on taste including level of taste disturbance (four studies using the VAS; one using Likert-type scale; one using the NRS), presence of taste disturbance (four studies using dichotomous scales), and satisfaction with

the ability to taste foods (one study using Likert-type scale) (Table 5). Impacts of dry mouth on denture retention, and development of dental caries were evaluated in three and two studies, respectively. One study used global oral health rating (five grades; poor to excellent) to assess overall impact of xerostomia on oral health.

5. Xerostomia-specific quality of life (COMET core area 30 – global quality of life)

Quality of life (QoL) domains related to assessment of xerostomia can be divided into xerostomia-specific QoL, oral health-related QoL, and general health-related QoL based on the specificity of the construct. Xerostomia-specific QoL encompasses QoL specific to the symptoms and/or conditions associated with xerostomia. The 15-item Xerostomia-related Quality-of-Life Scale (XeQoLS)³³ was the most frequently used xerostomia-specific QoL measurement instruments (15 studies), which evaluates four different QoL dimensions including physical functioning, psychological functioning, social functioning, and pain/discomfort. The 14-item Groningen Radiotherapy Induced Xerostomia (GRIX) questionnaire is the only condition-specific QoL instrument with an emphasis on the impact of xerostomia and sticky saliva during the day and night in patients with RIX³⁴, and has been used in five studies assessing RIX.

Four different modules of the European Organization for Research and Treatment of Cancer Quality of Life questionnaire (EORTC QLQ), which aims at measuring cancer-specific QoL, have been identified for use in studies assessing xerostomia outcomes. These include the core module (EORTC QLQ-C30 – used in 32 studies), the 35-item and 43-item Head and Neck Cancer (HNC) modules (EORTC QLQ-H&N35 – used in 46 studies; EORTC QLQ-H&N43 – used in one study), and the esophageal cancer module (EORTC QLQ-OES-18). Apart from the core module, other EORTC QLQ modules have certain items related to xerostomia, including presence and severity of dry mouth and sticky saliva, as well as limitation in oral function. Other HNC-specific measures with items assessing xerostomia identified in this systematic review include the University of Washington Quality of Life

Questionnaire (UW-QOL; ten studies), the Head and Neck Radiotherapy Questionnaire (HNRQ; two studies), the Head and Neck Quality of Life instrument (HNQOL; two studies), and the RTOG-modified University of Washington Head and Neck Symptom Score (RM-UWHNSS; one study) (Table 5).

6. Oral health-related quality of life (*COMET core area 30 – global quality of life*)

Overall, the 14-item Oral Health Impact Profile (OHIP-14) was the most frequently adopted oral health-related QoL measure, used in 25 included studies. This was followed by the Geriatric Oral Health Assessment Index (GOHAI; four studies), the Oral Impact on Daily Performance (OIDP; four studies), the 49-item Oral Health Impact Profile (OHIP-49; two studies) and the Oral Health-Related Quality of Life-UK (OHQOL-UK; two studies) (Table 5).

7. General health-related quality of life (*COMET core area 30 – global quality of life*)

General QoL measures applied in studies of xerostomia include the Medical Outcomes Study 36-Item Short Form Healthy Survey (SF-36; ten studies), the VAS for quality of life (two studies), and the following measures, each of which being used in one study: the Medical Outcomes Study 8-Item Short Form Healthy Survey (SF-8), the Symptom Checklist-90-Revised (SCL-90-R), the VAS for general well-being, and the World Health Organization Quality of Life Instrument, Short Form (WHOQOL-BREF) questionnaire (Table 5).

8. Patient satisfaction (*COMET core area 32 – delivery of care*)

The domain of patient satisfaction in the present study encompasses preference and satisfaction with symptom relief, functioning, and perception related to products used for xerostomia. The most frequently used scale for measuring symptom relief from the xerostomia products was the 100-mm VAS for symptom improvement, used in eight of the included studies. The categorical scale for assessing changes in symptomatology from baseline, the so-called Global Rating of Change (GRC), has been adopted with the response ranging from

three (worse/no change/better; four studies), to five categories (with added slightly worse/slightly better; one study) (Table 5).

Outcome measurements assessing multi-domain of xerostomia assessment

The present study identified 26 validated outcome measures assessing multiple aspects of xerostomia in the literature (Table 6), in addition, 68 articles used ad hoc instruments for the measurement of xerostomia unique to their studies. Within validated multi-domain outcome measures, physical functioning was the most commonly included domain of xerostomia assessment (23/26), followed by severity (17/26), and psychological functioning (10/26). The most frequently employed multi-domain xerostomia instrument was the Xerostomia Inventory by Thomson et al (XI; 68 studies)³², followed by the Xerostomia Questionnaire by Eisbruch et al (XQ; 31 studies)³⁵, the VAS-Xerostomia Questionnaire by Pai et al (VAS-XQ; 21 studies)³⁶ and the Summated Xerostomia Inventory by Thomson et al (SXI; 15 studies)³⁷.

In terms of the number of domains assessed, the Multidisciplinary Salivary Gland Society (MSGs) questionnaire³⁸ and the xerostomia assessment based on the study of Suh et al³⁹ measured the highest number of domains of xerostomia assessment, with each evaluating eight unique outcome domains. The location of xerostomia domain, which has no specific unidimensional outcome measures in the literature, has been included for assessment in a number of the recently developed multi-domain outcome instruments including the Regional Oral Dryness Inventory (RODI)⁴⁰, the MSGs questionnaire, or the NYU Bluestone Mouthfeel Questionnaire (BMQ)⁴¹.

C. Resource use core area (COMET core area 34 – economic)

There is a lack of studies assessing the economic aspect of having xerostomia. Only one study⁴² was identified to employ the EuroQol 5-domain 3L (EQ-5D-3L) for the calculation of quality-adjusted life-year (QALY), which aids in cost-effectiveness analysis of disease or treatment burden.

DISCUSSION

This systematic review revealed the diversity and variability in the domains and outcome measures used in clinical research on xerostomia. This is in accordance with general increasing recognition that insufficient attention has been paid to the choice and harmonization of outcome assessment in clinical studies, which might indicate methodological flaws in the synthesis of evidence-based clinical practice as a whole. The present study is a crucial prerequisite to systematically identifying existing knowledge on outcome domains and measures for the evaluation of xerostomia before future establishment of a promising COS specific for dry mouth.

The reporting of outcome domains and instruments varied considerably across studies assessing xerostomia. Among the 688 included studies, there were 16 unique outcome domains and 166 outcome measures extracted in the present systematic review. There were no single outcome domains or measures consistently utilized across all included studies. Surprisingly, there were 137 different outcome measures that were reported by three or fewer studies. This profoundly impedes evidence synthesis due to lack of comparability across studies. Nearly half of all clinical studies did not adequately describe or unclearly reports the domain of outcome assessment, reflecting that researchers often underestimate the importance to pre-specify the outcome of interest in clinical studies.

With respect to unique outcome domains, severity of xerostomia, physical functioning, and presence of xerostomia were the three most reported domains of xerostomia. However, the most frequently reported domain does not necessarily imply that the domain itself is important to the patients, nor that it should be included in all clinical studies of xerostomia. Also, apart from the localized symptoms, xerostomia can pose substantial impact on other aspects of life of affected individuals including emotional and social functioning ⁴³, which were found as an individual outcome in only three and nine studies in the xerostomia literature, respectively, and

thus under-represented. In addition, certain outcome domains were rarely examined in persons with xerostomia, particularly the economic aspect and location of symptoms.

Apart from wide variation across reporting outcomes, diversity within assessment of each outcome domain was also observed. For instance, severity of xerostomia was assessed in various points of interest including average and worst severity ratings, while the clinical relevance of each subdomain in the management of this condition remains under-investigated. The use and combination of outcome domains were heterogeneous between studies, implying that designing and reporting of xerostomia outcome in clinical trials is more or less based on specific intentions of researchers or subjective decisions of “what to measure” rather than having a systematic approach using inputs or engagement from investigators and more importantly patients, who are in fact recipients of the intervention.

There was also significant variation in the adoption of outcome measures for assessing each individual outcome domain. For example, there were 23 different outcome measures for assessing severity of xerostomia. The most extensively used outcome measure within the literature of xerostomia was the VAS (94 studies), followed by the Xerostomia Inventory (68 studies) and the RTOG/EORTC late radiation toxicity scoring for salivary gland (63 studies). Although being widely used in the literature, the RTOG/EORTC has some unclear scoring scheme including whether ‘response on stimulation’ requires chairside application of acid or mechanical stimuli ⁴⁴ or this can be subjectively graded by the investigator without additional clinical procedures ⁴⁵. This might result in difficulties when interpreting the findings and drawing conclusions derived from such outcome measures.

Different types of multi-domain questionnaires assessing xerostomia were utilized in the literature, with each assessing various combination of outcome domains of xerostomia. However, without knowledge of which outcome domains are considered important and relevant for the patients, healthcare providers and other stakeholders to be included in clinical

studies assessing intervention of xerostomia, the actual benefits of utilizing these outcome measures remain to be elucidated.

The current assessments of xerostomia appear to lack a standardized approach particularly in terms of operational definitions of xerostomia specific for clinical trials. This includes description of symptoms (e.g. oral dryness sensation, feeling lack of saliva, mouth stickiness), and temporal reference points (e.g. two weeks, three or six months). The ambiguity and variation of how xerostomia and its outcomes were described make analysis across studies challenging.

Certainly, inconsistencies in both reporting outcomes and selecting outcome measures hinder comparison and synthesis of robust evidence in systematic reviews and meta-analyses, which can be reliably performed only when clinical studies assess the same outcomes and measure them in the same way ⁴⁶. The outcome domains of xerostomia generated in the present review together with those of salivary gland hypofunction published in a separate systematic review ⁴⁷ can be taken forward to form a complete list of candidate outcome domains for dry mouth for further consensus processes in the development of COS by a multi-professional panel including patient representatives ⁴⁸. Clarification of “what to measure” and “how to measure” dry mouth in a set of outcomes validated by various stakeholders, will improve consistency in outcome domains and measures applied, minimize outcome reporting bias, improve quality and comparability between studies and provide recommendations for clinical practice.

To the best of our knowledge, this systematic review is the first study to provide a detailed, comprehensive summary of outcome domains and measures applied for the assessment of xerostomia in relevant clinical studies over the past two decades. The extensive variation in the range of outcomes applied in the literature of xerostomia have been underlined in previous Cochrane reviews ^{49, 50}. With the broad scope of search strategies and four databases searched, the results of this study are relevant and can be applicable to various treatments or interventions for xerostomia rather than confining itself to a single study type, treatment

modality, or etiologies of xerostomia. The methodological process of this study was guided by good practice as recommended by the Core Outcome Measures in Effectiveness Trials (COMET) handbook ⁴⁶. The core area and outcome domains extracted in the present study were mapped to the recently developed standard taxonomy for outcome classifications ²⁶.

The present study has several limitations. Despite our broad search strategies, this systematic review included only articles written in English in order to lessen issues associated with translating terms and thus may potentially fail to identify certain outcome domains reported in non-English publications. Additionally, with the aim to capture the diversity of outcomes and outcome measures available in the literature, included studies were not assessed on their scientific rigor. Due to a large number of publications related to xerostomia, we did not exhaustively include all the published articles, but our literature search was narrowed down to a period of the last 20 years. We assume, however, that any clinically relevant, important outcome measures would be carried over to the evaluated time period. Nonetheless, these limitations are unlikely to change the main findings and conclusions of this study.

CONCLUSION

There is a considerable heterogeneity in outcome domains and measures reported in clinical studies of xerostomia. This systematic review is the first step towards the development of a COS for the assessment of dry mouth in order to homogenize outcome reporting, standardize the conduct of individual trials, facilitate comparison across trials, and minimize research waste. This will ultimately support informed clinical decision in the management of dry mouth.

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Figure 1 Systematic review PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) flow diagram for literature search on outcome domains related to dry mouth

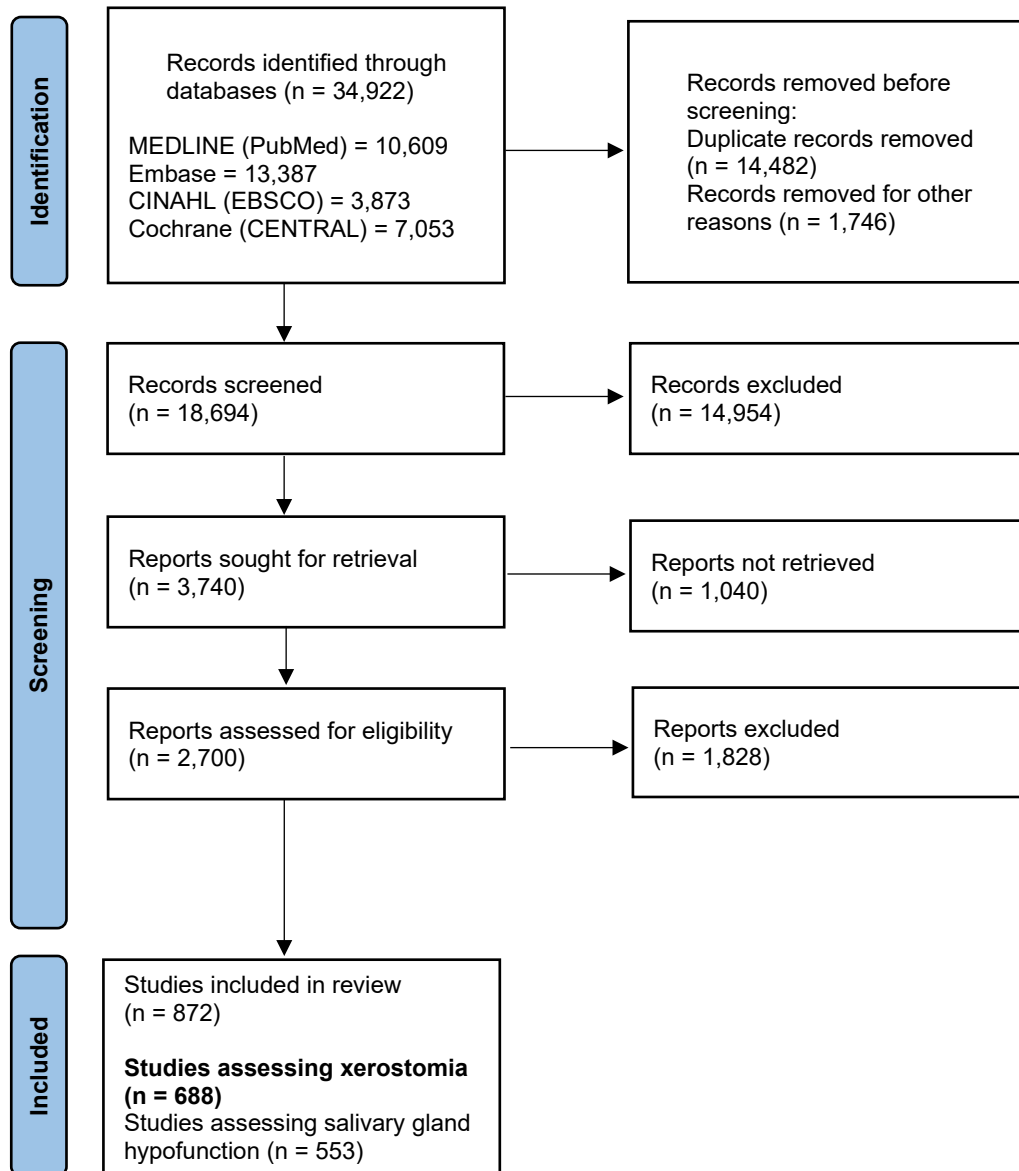
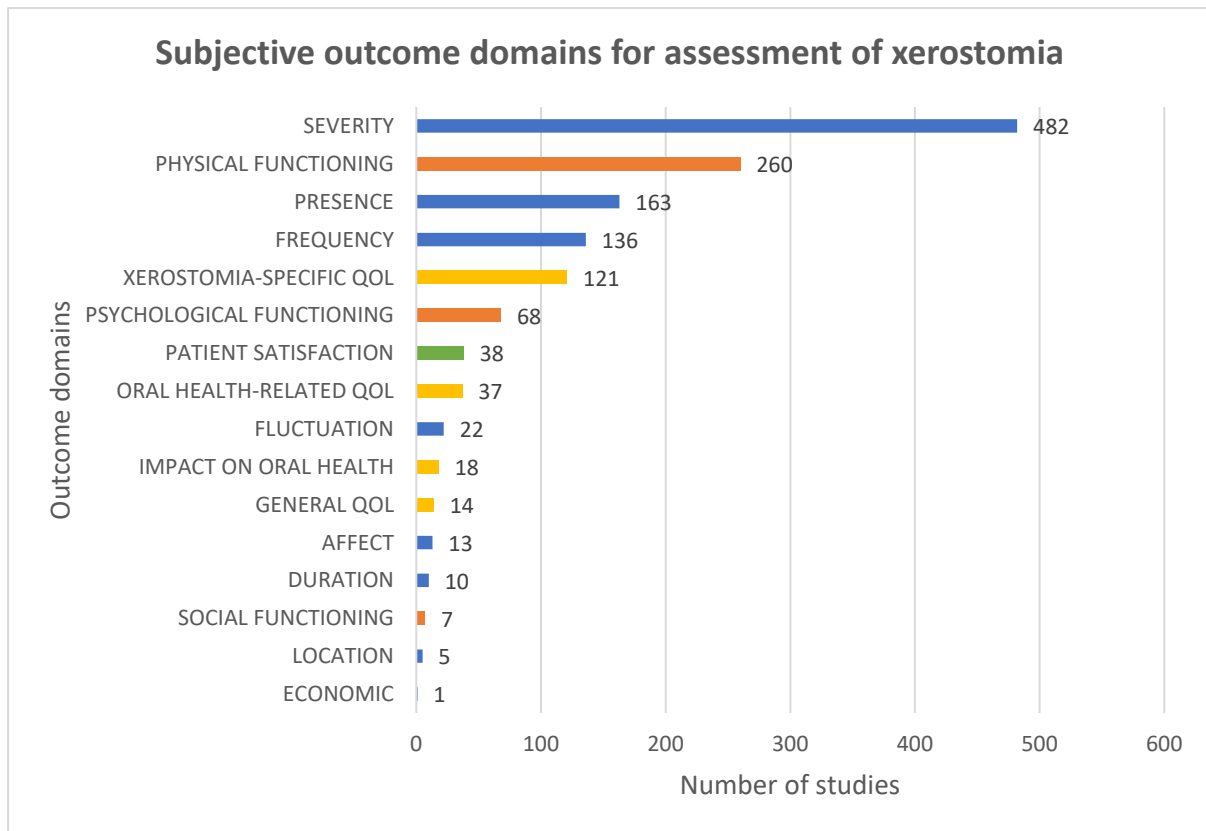


Figure 2 Number of studies assessing different outcome domains of xerostomia



QOL: Quality of life

Table 1 Characteristics of the included studies

Study characteristics	number (%)
<i>Year published</i>	
2001-2005	68 (9.9)
2006-2010	104 (15.1)
2011-2015	233 (33.9)
2016-2020	236 (34.3)
2021	47 (6.8)
2001-2010	172 (25.0)
2011-2020	469 (68.1)
2021	47 (6.8)
<i>Origin of the article</i>	
Africa	2 (0.3)
Asia	218 (31.7)
Europe	259 (37.6)
Multiple	17 (2.5)
North America	131 (19.0)
Oceania	17 (2.5)
South America	44 (6.4)
<i>Types of studies</i>	
Case-control studies	48 (7.0)
Case series	10 (1.4)
Cohort	258 (37.5)
Cross-sectional	160 (23.3)
Mixed-method	1 (0.1)
Qualitative	4 (0.6)
Quasi-experimental	3 (0.4)
Randomized controlled trials (RCTs)	146 (21.2)
Other types of clinical trials	50 (7.3)
Non-randomized	2 (0.3)
Non-controlled comparative	14 (2)
Crossover	22 (3.2)
Single-arm	12 (1.7)
Validation	8 (1.2)
<i>Conditions associated with dry mouth</i>	
Older age	45 (6.5)
Polypharmacy	26 (3.8)
Radiation to the head and neck	244 (35.5)
Sjögren's disease	98 (14.2)
Other conditions	127 (18.5)
Several disease groups	76 (11.0)
Unknown etiology of dry mouth	72 (10.5)
<i>What is the article assessing</i>	
Xerostomia and salivary gland hypofunction	380 (55.2)
Xerostomia only	308 (44.8)

Table 2 Unique outcome domains assessing xerostomia mapped to the COMET (Core Outcome Measures in Effectiveness Trials) taxonomy

Subjective outcome domains for the assessment of xerostomia
<i>Physiological/clinical core area, 8: Gastrointestinal outcomes (xerostomia core area)</i>
1. Xerostomia (presence/unspecified)
2. Severity of xerostomia
3. Affect of xerostomia
4. Frequency of xerostomia
5. Duration of xerostomia
6. Fluctuation of xerostomia
7. Location of xerostomia
<i>Life impact core area, 25: Physical functioning</i>
8. Physical functioning
<i>Life impact core area, 26: Social functioning</i>
9. Social functioning
<i>Life impact core area, 28: Emotional functioning/well-being</i>
10. Psychological functioning
<i>Life impact core area, 30: Global quality of life</i>
11. Impact on oral health
12. Xerostomia-specific quality of life
13. Oral health-related quality of life
14. General health-related quality of life
<i>Life impact core area, 32: Delivery of care</i>
15. Patient satisfaction ^H
<i>Resource use core area, 34: Economic</i>
16. Economic

Table 3 Patient-reported unidimensional outcome measurements related to xerostomia core area

Outcome domains	Outcome measures	Level of measurement/ response options	Number of studies	Reference
Presence of xerostomia				
		<i>dichotomous</i>		
	<i>Single question</i>	yes/no		
	Are you normally aware of your dry mouth?		1	51
	Does your mouth (usually) feel dry?		11	52-62
	Does the amount of saliva in your mouth seem to be too little?		1	63
	Do you feel dryness of the mouth?		1	64
	Do you feel that your mouth is dry frequently?		1	65
	Do you often have dry mouth?		1	66
	Do you think you have a dry mouth?		1	67
	During the past 2 weeks, have you at any time felt your mouth to be dry?		1	68
	During the last 2 weeks, have you had a dry mouth?		1	69
	Have you had a dry mouth sensation every day for the last 3 months?		1	70
	Have you had a dry mouth sensation every day for the last 6 months?		2	71, 72
	Have you had a persistent dry mouth for more than 3 months?		1	73
	Have you ever been diagnosed by a dentist or doctor with dry mouth?		1	67
	Have you had a daily feeling of dry mouth for more than three months?		40	74-113
	Have you suffered from a persistent dry mouth for the previous three months?		1	114
	Has your mouth been abnormally dry, even if you have been drinking enough water?		1	115
	Is your mouth dry?		1	116
	<i>Unspecified/ad hoc question</i>	yes/no		
	Presence of dry mouth complaint (ad hoc)		46	117-162
		<i>categorical</i>		
	Do you think you have healthy saliva flow?	yes/no/don't know	1	67
	Does the amount of saliva in your mouth seem to be too little, too much, or you don't notice it?	too little/too much/you don't notice it	1	163
	How would you describe the amount of saliva in your mouth?	few/normal/much	2	71, 164
	Patient's classification of one's own oral status	moist (normal)/dry/do not notice	1	165
Severity of xerostomia				
		<i>categorical</i>		
	<i>Single question</i>			
	Do you feel that you have enough saliva in your mouth?	no/mild/moderate/severe	1	166
	Does your saliva often feel thick?	no/mild/moderate/severe	1	166

	Have you had a dry mouth? Item from EORTC QLQ-H&N43	not at all/a little/quite a bit/very much	1	167
	<i>Unspecified/ad hoc question</i>			
	Level of discomfort from xerostomia	extremely uncomfortable/moderately uncomfortable/little/no discomfort	1	115
	Severity of dry mouth (ad hoc)	mild/moderate/severe	3	166, 168, 169
		none/mild/severe	1	170
		never dry/moderate/severe	1	171
		none/a bit/quite a bit/a lot	1	172
		not dry/somewhat dry/very dry	1	173
		1-5 (mild to severe xerostomia)	1	174
		0-4 (none/absent to severe)	2	175, 176
		0-4 (absent/slight/moderate/rather severe/Maximum discomfort)	1	177
		0-3 (no feeling/slight/moderate/severe)	1	178
		<i>numerical/continuous</i>		
	<i>Validated/established scale</i>			
	The Dry Mouth Inventory (DMI) 1. No moisture in the mouth 2. Lips sticking to roof of mouth 3. Tongue sticking to roof of mouth 4. Throat dry	strongly disagree/disagree/disagree a little/ agree a little/agree/strongly agree	1	179
	How severe has your dryness been during the last 2 weeks? The EULAR Sjogren's Syndrome Patient Reported Index (ESSPRI)	0-10	33	42, 98, 160, 180-209
	Your having a dry mouth at its worst The MD Anderson Symptom Inventory-Head and Neck Module (MDASI-HN)	0-10	7	209-215
	Numerical rating scale (NRS) for xerostomia	0-10	18	89, 122, 149, 216-230
	Visual analog scale (VAS) for xerostomia	0-100 mm/ 0-10 cm	94	18, 19, 42, 62, 190, 196, 199, 201, 206, 231-314
	Semi-quantal scale for xerostomia	0-6	1	315
	11-point colorimetric scale for xerostomia	0-10	1	316
	VAS for burning sensation	0-100 mm	4	235, 242, 272, 276
	VAS for oral discomfort from dry mouth	0-100 mm	7	18, 281, 283, 289, 317-319
	11-point colorimetric scale for oral discomfort	0-10	1	316
		unclear		
	Severity of dry mouth	by interview	1	43
Affect of xerostomia				
		<i>Categorical</i>		
	<i>Single question</i>			
	Do you have problems with dryness of the mouth?	no feeling/slight feeling/severe feeling/ troublesome feeling of dry mouth	1	320

	<i>Validated/established scale</i>			
	Face scale on the feeling of oral dryness	7 drawings from smiley face (no feeling) to tearful face (severe feeling)	1	321
		<i>Numerical/continuous</i>		
	<i>Single question</i>			
	Bother 1 index On the scale of 0-10, how much of your dry mouth problem bothering you?	0-10	3	322-324
	<i>Validated/established scale</i>			
	<i>unspecified/ad hoc question</i>	<i>unknown</i>		
	affect of xerostomia	by interview	1	325
Frequency of xerostomia				
		<i>categorical</i>		
	<i>Single question</i>			
	Does your mouth feel dry?	no/occasionally/continuously	1	326
	How often does your mouth feel dry?	never/occasionally/frequently/always	20	1, 18, 31, 171, 281, 302, 314, 327-340
	<i>Unspecified/ad hoc question</i>			
	Daily frequency of oral dryness	never/hardly ever/occasionally/fairly often/very often	1	177
	Pattern of xerostomia	every day/intermittent/continuous/once	1	169
		<i>unknown</i>		
	Frequency of xerostomia	by interview	2	174, 341
Duration of xerostomia				
		<i>categorical</i>		
	<i>Single question</i>			
	Since when have you experienced dryness in the mouth?	recently/several months/several years/ 10 years or more	1	171
	<i>Unspecified/ad hoc question</i>	<i>unknown</i>		
	Duration of xerostomia	by interview	3	97, 123, 174
Fluctuation of xerostomia				
		<i>dichotomous</i>		
	<i>Unspecified/ad hoc question</i>	yes/no		
	Comparison of dry mouth symptoms during the day and night		1	235
	Presence of dry mouth in the daytime		1	235
	Presence of dry mouth when eating		4	243, 342-344
	Presence of dry mouth when waking		1	345
	Presence of nocturnal xerostomia - any symptoms of oral dryness during night-time and/or frequent wake-ups feeling thirst		2	235, 346
		<i>categorical</i>		
	<i>Single question</i>			
	Do you have a dry mouth at night?	1 - 5 (no complaint to always present)	1	347

	Do you have a dry mouth during the day?	1 - 5 (no complaint to always present)	1	347
	Does your mouth usually feel dry at night?	yes often/yes sometimes/no seldom/no never	3	4, 348, 349
	Does your mouth usually feel dry in the daytime?	yes often/yes sometimes/no seldom/no never	3	4, 348, 349
	<i>Unspecified/ad hoc question</i>			
	Presence of dry mouth during the day/daytime xerostomia	never/occasionally/quite often/always	1	350
		0-3 (no to severe oral dryness)	1	346
	Presence of dry mouth on waking up	never/occasionally/quite often/always	1	350
		<i>numerical/continuous</i>		
	<i>Single question</i>			
	How comfortable does your mouth feel in the following situations? at night before bed during the night on waking	0-10 (no discomfort to extreme discomfort)	1	351

Table 4 Investigator-graded outcome measurements related to xerostomia core area

Outcome domains	Outcome measures	Level of measurement/ response options	Number of studies	Reference
Investigator-graded outcome measures for xerostomia core area				
Severity of dry mouth				
		<i>categorical</i>		
	<i>Single question</i>			
	<i>Validated/established criteria</i>			
	The Common Terminology Criteria for Adverse Events (CTCAE) radiation morbidity grading scale for dry mouth/salivary gland (xerostomia)	Grade 1 (mild) - symptomatic (dry or thick saliva) without significant dietary alteration Grade 2 (moderate) – moderate symptoms; oral intake alteration (e.g. copious water, other lubricants, a diet limited to purees and/or soft moist foods) Grade 3 (severe) - symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or parenteral nutrition indicated	41	352-392
	The Late Effects in Normal Tissue-Subjective, Objective, Management and Analytical (LENT-SOMA) systems for grading of dry mouth	1 - normal moisture 2 - scant saliva 3 - absence of moisture; sticky, viscous saliva 4 - absence of moisture; coated mucosa	6	379, 380, 382, 387, 388, 393
	The Observer-rated Xerostomia Scale (XS) dryness of the oral mucosa redness of the oral mucosa oral ulcer coating of the tongue surface smoothing of the tongue surface wrinkles and creases on the tongue surface cracks on the tongue surface redness of the oral mucosa dryness of the mucosa of the oropharynx	0-3 (no complaints or normal to severe discomfort or worse findings)	1	394
	The Oral Assessment Guide (OAG) oral dryness (lips, tongue, mucous membrane) saliva	Oral dryness 1-3 (normal to severe oral dryness) Saliva 1-3 (watery/thick or ropy/absent)	1	342

	The Oral Assessment Protocol oral mucous membrane comfort lips/corners of mouth tongue saliva/dry mouth swallow/chewing candida infection teeth/denture	Oral mucous membrane (pink and moist with firm gums/reddened or edema or radiation plaque/ulceration or bleeding) Comfort (comfortable/discomfort/pain) Lips/corners of mouth (smooth, pink, moist/dry or cracked/ulcerated or bleeding/herpes simplex) Tongue (pink and moist/coated/blistered or cracked) Saliva/dry mouth (watery/thick and ropey/absent or dry mouth) Swallow/chewing (normal/unable to swallow normal diet/unable to swallow liquid diet/unable to swallow fluids/unable to swallow saliva) Candida/infection (no/yes) Teeth/denture (clean, no debris/loose teeth or ill-fitting dentures/debris/caries)	1	395
	The Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer (RTOG/EORTC) acute radiation morbidity scoring scheme for salivary gland (acute xerostomia/salivary gland toxicity)	Grade 0 – no change over baseline Grade 1 – mild mouth dryness/slightly thickened saliva/may have slightly altered taste such as metallic taste/these changes not reflected in alteration in baseline feeding behavior, such as increased use of liquids with meals	30	396-425
	The Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer (RTOG/EORTC) late radiation morbidity scoring scheme for salivary gland (late xerostomia/salivary gland toxicity)	Grade 0 - none Grade 1 - slight dryness of the mouth; good response on stimulation Grade 2 - moderate dryness of the mouth; poor response on stimulation Grade 3 - complete dryness of mouth; no response on stimulation	63	45, 359, 383, 387, 388, 396, 397, 399-407, 409, 410, 415, 417-421, 423-460, 461, 462
	The Subjective dry mouth grading by Eisbruch et al	Grade I - no disability Grade II - dryness requiring additional fluids for swallowing Grade III - dryness causing dietary alterations or interference with sleep, speaking, or other activities	5	463-467
	The Wang Zhong-He scoring criteria for xerostomia	0 - none 1 - mild dryness of the mouth when sleeping at night or waking up in the morning. 2 - mild dryness, no effect on eating or speaking 3 - moderate dryness, drinking water necessary when eating or speaking. 4 - severe dryness, burning mouth, dysphasia, drinking water necessary.	1	468
	<i>Unspecified/ad hoc question</i>			

	severity of xerostomia	<p>mild - noticeable but does not influence daily activities and usually does not need intervention</p> <p>moderate - sufficiently troublesome to make the person uncomfortable; it may influence performance of daily activities; and it may need intervention</p> <p>severe - cause severe discomfort; it usually interferes with daily activities; it usually needs treatment or intervention</p>	1	469
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Table 5 Patient-reported unidimensional outcome measurements related to life impact core area

Outcome domains	Outcome measures	Level of measurement/ response options	Number of studies	Reference
Unidimensional patient-reported outcome measures for life impact core area				
<i>Physical functioning</i>				
		<i>dichotomous</i>		
	<i>Unspecified/ad hoc question</i>	yes/no		
	Ability to chew apples/dried fruits/roast beef without difficulty		1	470
	Ability to chew French bread/rice crackers/pickled vegetables/peanuts without difficulty		1	60
	Difficulty with chewing		2	58, 60
	Difficulty eating		1	52
	Difficulty speaking		2	58, 60
	Difficulty swallowing		5	58, 71, 164, 318, 471
	Difficulty swallowing dry foods		2	151, 472
	Need to drink liquids to aid in swallowing		4	71, 164, 318, 471
		<i>categorical</i>		
	<i>Unspecified/ad hoc question</i>			
	Difficulty swallowing/speaking for relatively long periods of time	no/mild/moderate/severe	1	166
	Satisfaction with the ability to chew/speak clearly	satisfied/fairly satisfied/dissatisfied	1	470
	Need to drink water for speaking/swallowing/during ordinary time	not at all/rather no/rather yes/very yes	1	473
	<i>Validated/established scale</i>	<i>continuous</i>		
	Assessment of Intelligibility of Dysarthric Speech (AIDS)		1	474
	NRS for difficulty swallowing	0-10	1	220
	The Robertson Dysarthria Profile (RDP)		1	474
	VAS for difficulty speaking	0-100 mm	8	18, 232, 235, 242, 244, 276, 281, 289
	VAS for difficulty chewing	0-100 mm	5	232, 235, 242, 272, 276
	VAS for ability to swallow/difficulty swallowing	0-100 mm	8	18, 235, 242, 244, 272, 276, 281, 289
	VAS for requirement to sip water when speaking, when chewing and swallowing, and even during sleep time	0-100mm	1	270
	11-point colorimetric scale for difficulty eating, swallowing, need for additional water	0-10	1	316
		<i>unknown</i>		
	Physical functioning	by interview	1	43
<i>Social functioning</i>				
		<i>dichotomous</i>		
	<i>Unspecified/ad hoc question</i>	yes/no		

	Avoid speaking to people due to dry mouth		1	235
	Stay at home more due to dry mouth		1	235
	Visit people less frequently due to dry mouth		1	235
		<i>unknown</i>		
	<i>Unspecified/ad hoc question</i>			
	Social interaction/social functioning	by interview	2	43, 325
<i>Psychological functioning</i>				
		<i>categorical</i>		
	<i>Unspecified/ad hoc question</i>			
	Difficulty in initiating sleep due to dry mouth at night?	not at all/rather no/rather yes/very yes	1	473
		<i>numerical/continuous</i>		
	<i>Unspecified/ad hoc question</i>			
	During the past week, how many times on average did you wake up in the night due to dryness of your mouth?	number of times	2	18, 281
		<i>Validated/established scale</i>		
	Hospital Anxiety and Depression Scale (HADS)		3	474-476
	VAS for ability to sleep	0-100 mm	1	232
	<i>Unspecified/ad hoc question</i>			
	Psychological response/psychological functioning	by interview	2	43, 325
<i>Impact on oral health</i>				
		dichotomous		
	<i>Unspecified/ad hoc question</i>	yes/no		
	Changes in sweet, salty, sour or bitter taste?		1	316
	Impact on denture retention		1	235
	Taste disturbance in the mouth		3	62, 151, 305
		<i>categorical</i>		
	<i>Unspecified/ad hoc question</i>			
	Difficulty with taste	no/mild/moderate/severe	1	166
	Satisfaction with the ability to taste foods	satisfied/fairly satisfied/dissatisfied	1	470
	Suffer from dental caries	no/mild/moderate/severe	1	166
		<i>Validated/established scale</i>		
	Global oral health rating	0-4 (poor to excellent)	1	474
		<i>Validated/established scale</i>		
	NRS for impact/alteration on taste	0-10	1	220
	VAS for difficulty wearing dentures	0-100mm	2	244, 276
	VAS for impact/alteration on taste	0-100 mm	4	235, 242, 276, 303
	VAS for severity of suffer from tooth decay	0-100 mm (hardly to highly)	1	244
	<i>Unspecified/ad hoc question</i>	<i>unknown</i>		

	Impact on dental and oral health	by interview	1	174
<i>Xerostomia-specific QoL</i>				
		<i>categorical</i>		
	<i>Validated/established scale</i>			
	The European Organization for Research and Treatment of Cancer Quality of Life questionnaire Core Module (EORTC QLQ-C30)		32	355, 357, 360, 369, 391, 405, 410, 411, 428, 429, 475, 477-497
	The European Organization for Research and Treatment of Cancer Quality of Life questionnaire Head and Neck Module (EORTC QLQ-H&N35)		46	216, 221, 352, 355, 357, 360, 396, 405, 410, 411, 421, 428, 458, 475, 478, 480, 481, 484-496, 498-513
	The European Organization for Research and Treatment of Cancer Quality of Life questionnaire Head and Neck Module (EORTC QLQ-H&N43)		1	391
	The European Organization for Research and Treatment of Cancer Quality of Life questionnaire OESophageal Cancer Module (EORTC QLQ-OES18)		3	493, 514, 515
	The Groningen Radiotherapy Induced Xerostomia (GRIX) questionnaire		5	510, 511, 516-518
	The Head and Neck Quality of Life Questionnaire (HNQOL)		2	389, 519
	The Head and Neck Radiotherapy Questionnaire (HNRQ)		2	259, 520
	the RTOG-modified University of Washington Head and Neck Symptom Score (RM-UWHNSS)		1	521
	The Sjögren's Syndrome Symptom Survey		1	522
	The University of Washington Quality of Life Questionnaire (UW-QOL)		10	16, 307, 389, 425, 459, 468, 483, 523-525
	The Xerostomia related Quality of Life Scale (XeQOLS)		15	202, 222, 385, 523, 524, 526-535
		<i>numerical/continuous</i>		
	VAS for influence of dry mouth on general well-being	0-100mm	1	286
		Unknown		
	Experience of xerostomia	by interview	1	418
<i>Oral health-related QoL</i>				
		<i>numerical/continuous</i>		
	The Geriatric Oral Health Assessment Index (GOHAI)		4	266, 536-538
	The Oral Health Impact Profile-14 (OHIP-14)		25	71, 89, 164, 209, 217, 241, 299, 301, 327, 474, 476, 531, 539-551
	The Oral Health Impact Profile-49 (OHIP-49)		2	16, 220
	The Oral Health Related Quality of Life-UK (OHQOL-UK)		2	209, 476
	The Oral Impact on Daily Performance (OIDP)		4	124, 209, 349, 474, 552
<i>General QoL</i>				
	<i>Validated/established scale</i>	<i>numerical/continuous</i>		

	Medical Outcomes Study 8-Item Short Form Healthy Survey (SF-8)		1	222
	Medical Outcomes Study 36-Item Short Form Healthy Survey (SF-36)		10	146, 239, 240, 478, 522, 536, 553-556
	The Symptom Checklist-90-Revised (SCL-90-R)		1	556
	VAS for general well-being	0-100mm	1	286
	VAS for quality of life	0-100mm	2	18, 281
	The World Health Organization Quality of Life Instrument, Short Form (WHOQOL-BREF) questionnaire		1	476
<i>Patient satisfaction</i>				
		<i>dichotomous</i>		
	<i>Unspecified/ad hoc questions</i>	yes/no		
	Easiness to use of the product		3	235, 306, 309
	Symptom improvement after use of the product		4	235, 306, 309, 472
	Willingness to take medication for a long-term basis		1	536
		<i>categorical</i>		
	<i>Single question</i>			
	How did your dry mouth feel after the treatment?	worse/no change/better/much better	2	168, 251
	<i>Validated/established criteria</i>			
	Change from baseline symptomatology related to dry mouth sensation	worse/no change/better	4	232, 289, 557, 558
		worsening/unchanged/slight improvement/ significant improvement	1	177
		better/slightly better/unchanged/slightly worse/ worse	1	303
	Product Performance and Attribute Questionnaire (PPAQ)		2	179, 559
	Product Performance Questionnaire (PPQ)		1	560
	<i>Unspecified/ad hoc questions</i>			
	Comparison between the effect of treatment	the effect of both experiments was similar/ the first had a better effect on my dryness/ the second had a better effect on my dryness	1	53
		<i>numerical/continuous</i>		
	<i>Validated/established criteria</i>			
	VAS for easiness to use the product	0-100mm	1	561
	VAS for effect of the product on symptom relief	0-100mm	8	235, 289, 306, 309, 536, 561-563
	VAS for pleasantness of the taste of the product	0-100mm	4	235, 306, 309, 561

	<i>Unspecified/ad hoc questionnaires</i>			
	Patient satisfaction		4	553, 564-566
		<i>unknown</i>		
	Change in symptoms with treatment	By interview	2	174, 267

Table 6 Patient-reported multi-domain outcome measurements for the assessment of xerostomia

Outcome measures	Outcome domains													Level of measurement	No. of studies	References	
	Xerostomia core area						Life impact core area										
	Presence	Severity	Affect	Frequency	Duration	Fluctuation	Location	Physical functioning	Social functioning	Psychological functioning	Impact on oral health	Xerostomia-specific QoL	Oral health-related QoL				General health-related QoL
Dry Mouth Questionnaire (DMQ) Part 1: Xerostomia assessment How dry is your mouth? <i>very dry-not dry</i> For the following items: <i>very severe-never</i> Are you suffering from oral dryness during daytime? Are you suffering from oral dryness at night? Do you have a nasty taste in your mouth? Is sleeping/swallowing/eating impeded? Part2: effectiveness of treatment How frequently do you apply the substitute? ... <i>times per day</i> For how long is your mouth moist after applying the substitute? ... <i>min</i> Is the extent of oral dryness reduced when applying the substitute? <i>highly-not reduced</i> How dry is your mouth when applying the substitute? <i>very severe-not dry</i> How do you appreciate the taste of the substitute? <i>very palatable-nasty</i> What complaints are reduced when using the substitute? For the following items: <i>very severe-never</i> Dryness during daytime/dryness at night/burning mouth/nasty taste/sleeping difficulties/difficulties with speech/difficulties with swallowing/difficulties with eating		X				X		X		X				X	0-4	5	567-571
Dry Mouth Symptom Score (DMSS) The following 2 questions are applied to each symptom: In the past week, how often have you had these problems? In the past week, how bothered were you by these problems? dry mouth/difficulty in speaking/difficulty in swallowing/difficulty in sleeping/bad breath/difficulty in wearing dentures/dry throat			X	X			X		X	X					1-7 (never-always)	1	572
McMaster University Head and Neck Radiotherapy Questionnaire (HNRQ)		X	X				X								0-100mm/0-10	4	137, 259, 520, 573

<p>During the past week, overall, your mouth or tongue was: (<i>very dry-not dry</i>)</p> <p>In general, during the past week, the feeling of your mouth and tongue was: (<i>extremely uncomfortable-comfortable</i>)</p> <p>During the past week, overall, due to the dryness of your mouth and tongue, how difficult was it to speak without drinking liquids: (<i>very difficult-easy</i>)</p> <p>During the past week, overall, due to the dryness of your mouth and tongue, how difficult was it to chew and swallow food: (<i>very difficult-easy</i>)</p> <p>The overall condition of your xerostomia (dry mouth) is: (<i>very uncomfortable-comfortable</i>)</p>																				
<p>Memorial Symptom Assessment Scale (MSAS)</p> <p>During the past week, did you have symptom of dry mouth? <i>yes/no</i></p> <p>If yes, how often did you have it? (1-4 <i>rarely-almost constantly</i>)</p> <p>If yes, how severe was it usually? (1-4 <i>slight-very severe</i>)</p> <p>If yes, how much did it distress or bother you? (0-4 <i>not at all-very much</i>)</p>	X	X	X	X														different response options in each item	1	574
<p>Mouth Dryness Questionnaire (MDQ) by Walizer et al</p> <p>questions relating to dryness at different times of the day, and while sleeping, eating, speaking, and other activities of daily living</p>		X				X		X		X								1-4	1	342
<p>Multidisciplinary Salivary Gland Society (MSGSS) questionnaire</p> <p>20 items with 13 items related to dry mouth</p> <p>Since 1 month</p> <p>Evaluate the intensity of your mouth dryness (<i>no dryness-maximal dryness</i>)</p> <p>Evaluate the frequency of your mouth dryness during the day (<i>never-constantly during the day</i>)</p> <p>Evaluate the quality of your saliva (<i>normal (even if diminished)-very thick/sticky/watery (serous)/no saliva</i>)</p> <p>Evaluate the taste of your saliva (<i>normal-very salty and/or sweet and/or bitter and/or acid and/or bad taste</i>)</p> <p>At which frequency do you feel the need to moisture your mouth during the day (either by drinking water / chewing gums / or by using moisturizing sprays)? (<i>never-constantly</i>)</p> <p>How frequently do you wake up at night to drink water? (<i>never-very frequently</i>)</p> <p>Evaluate your talking difficulty related to your dry mouth (<i>no difficulty-very important difficulty (constant need to moisturize to be able to speak)</i>)</p> <p>Evaluate your level of difficulty to chew and swallow food (<i>No difficulty-very important difficulty (constant need to drink water to chew and swallow food)</i>)</p> <p>Evaluate the dryness of your lips (<i>no dryness-maximal dryness</i>)</p> <p>Evaluate the dryness of your nose (<i>no dryness-maximal dryness</i>)</p>		X		X		X	X	X		X	X	X						0-10	1	38

Evaluate the dryness of your eyes (<i>no dryness-maximal dryness</i>) Are your physical activities disturbed because of your dry mouth? (<i>no-yes, I avoid any activity which makes me uncomfortable because of my dry mouth</i>) Evaluate your quality of life regarding to your dry mouth (<i>perfect-completely unsatisfying</i>)																				
New York University (NYU) Bluestone Mouthfeel Questionnaire (BMQ) My mouth feels fresh My mouth feels dry My mouth feels tingly My mouth feels moist My mouth feels stale My lips feel dry My mouth feels clean My saliva feels thick and pasty I have difficulty swallowing I have plenty of saliva My mouth feels sticky		X	X				X	X										0-100mm	1	575
Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) for dry mouth Please think back over the past 7 days How often did you have dry mouth? (<i>never/rarely/occasionally/frequently/almost constantly</i>) What was the severity of your dry mouth at its worst? (<i>none/mild/moderate/severe/very severe</i>) How much did dry mouth interfere with your usual or daily activities? (<i>not at all/a little bit/somewhat/quite a bit/very much</i>)		X		X							X							0-4	1	378
Profile of Fatigue and Discomfort – Sicca Symptoms Inventory (short form) (PROFAD-SSI-SF) 19 items with 5 items on oral dryness (full questionnaire is not available online)		X					X											0-7	1	576
Regional Oral Dryness Inventory (RODI) upper lip, lower lip, inside of the cheeks, front part of the palate, back part of the palate, front part of the tongue, back part of the tongue, floor of the mouth, throat		X					X											1-5 (no dryness - severe dryness)	2	40, 322
Salivary Gland Symptom Questionnaire Have you experienced the following in the last 3 months Dry mouth/altered taste/lack of taste/metallic or bitter taste/difficulty in swallowing dry foods (e.g.bread, crackers)/ difficulty speaking/pain in the salivary glands under the jaw/ painful mouth or ulcers in the mouth/pain with swallowing/ swelling in the salivary glands in front of the ears/swelling in the salivary glands under the jaw Please answer yes or no to the following questions Have you had cavities filled by your dentist in the last 3 months?	X						X			X								yes/no	1	577

Have you needed to carry bottled water or drinks with you in the last 3 months? During the last 3 months have you routinely chewed gum or sucked candies?																	
Sicca Symptom Inventory (SSI) 42 items with 24 items related to dry mouth Rate the frequency of experience of each symptom item over the last 2 weeks (0-4 <i>never-all the time</i>) Rate the overall severity of each group of symptoms over the last 2 weeks (0-7 <i>no problem at all-as bad as imaginable</i>) Difficulty eating (oral facet 1): mouth felt dry when eating/difficulty eating certain food/difficulty swallowing dry food/liquid helps to swallow/food stuck in mouth/need to rinse away food/appreciated food less Dry throat (oral facet 2): mouth felt dry when breathing/difficulty talking/had to drink to speak easily/nose felt dry/throat dry/air-conditioning dries mouth Bad breath (oral facet 3): saliva felt sticky/breath smelt Wetting mouth (oral facet 4): carried drinks to bed/needed drinks during the night/woke at night to pass urine/urgent need to pass urine Oral problems (oral facet 5): ulcers in the mouth/swollen salivary glands/felt as though choking/change in flavors or taste/visited the dentist		X		X				X		X	X						0-4 (frequency), 0-7 (severity)
Summated Xerostomia Inventory (SXI) My mouths feel dry when eating a meal My mouth feels dry I have difficulty in eating dry foods I have difficulties swallowing certain foods My lips feel dry				X				X									1 - never 2 - occasionally 3 - often
Vanderbilt Head and Neck Symptom Survey (VHNSS) 48 items with multiple domains including dry mouth domain Dry mouth Dry mouth makes chewing and swallowing difficult Dry mouth affects sleep Dry mouth affects speech Mouth sensitive to dryness		X						X		X							0-10
VAS-Xerostomia Questionnaire (VAS-XQ) by Pai et al Rate the difficulty you experience in speaking due to dryness Rate the difficulty you experience in swallowing due to dryness Rate how much saliva is in your mouth Rate the dryness in your mouth Rate the dryness in your throat Rate the dryness of your lips Rate the dryness of your tongue Rate the level of your thirst		X					X	X									0-100 mm
Xerostomia assessment by Amosson et al What is the overall comfort of your mouth?	X	X					X		X	X							yes/no
																	187, 208, 578, 579
																	229, 334, 337, 538, 550, 580-588
																	589-595
																	138, 202, 215, 270, 275, 297, 339, 392, 526, 527, 531, 539-541, 548, 549, 596-600
																	462, 601-603

<p>Does your mouth feel dry when eating? Do you have difficulty swallowing any foods? Do you need to sip liquids to swallow dry food? Do you feel thirsty all the time? Do you feel the amount of saliva in your mouth is too little, too much, or adequate? Do you have problems with speech because of dry mouth? Does dry mouth interfere with your ability to sleep all the time? Has your taste changed as a result of salivary gland function? Do you need to carry water daily?</p>																		For item1: very comfortable/slight moderate/severe dryness		
<p>Xerostomia assessment by Artico et al Have you had a daily feeling of dry mouth for more than 3 months? Have you been experiencing difficulty in swallowing dry foods? Do you frequently drink liquids to aid swallowing dry foods? Do you wake up at night to drink water?</p>	X						X											yes/no	2	93, 95
<p>Xerostomia assessment by Berti-Couto et al Does your mouth feel dry? Do you experience any difficulties chewing dry foods? Do you experience any difficulties swallowing dryfoods? Are you aware of any recent increase in the frequency of liquid intake?</p>	X						X											yes/no	3	604-606
<p>Xerostomia assessment by Campisi et al Do you feel your mouth is dry? Do you have difficulty eating certain foods? Do you have difficulty swallowing certain foods? Do you use water to help when swallowing certain foods? Do you use water to rinse away debris?</p>		X					X											not at all/a little/ quite a bit/very much	1	607
<p>Xerostomia assessment by Fox et al Does your mouth feel dry at night or on awakening? Does your mouth feel dry at other times of the day? Do you keep a glass of water by your bed? Do you sip liquids to aid in swallowing dry foods? Does your mouth feel dry when eating a meal? Do you have difficulties swallowing any foods? Do you chew gum daily to relieve oral dryness? Do you use hard candies or mints daily to relieve oral dryness? Does the amount of saliva in your mouth seem to be too little, too much, or you don't notice it?</p>	X					X	X											yes/no	11	275, 546, 564, 608-615
<p>Xerostomia assessment by Fox et al (5 item version) Does your mouth usually feel dry? Does your mouth feel dry when eating a meal? Do you have difficulties swallowing any foods? Do you sip liquids to aid in swallowing dry foods? Does the amount of saliva in your mouth seem to be too little, too much, or you don't notice it?</p>	X					X	X											yes/no	5	91, 282, 343, 425, 616

<p>Xerostomia assessment by Suh et al Duration of oral dryness (recently/several months/several years) Frequency of oral dryness (occasionally/frequently/always) Intensity of oral dryness symptoms and impact (VAS) at night or on awakening (Dry-PM), at other times of the day (Dry-day), during eating (Dry-eat) VAS for difficulties in swallowing food (Dif-swal) VAS for amount of saliva in usual, everyday life (Am-sal) VAS for effect of oral dryness on daily life (Eff-life) Awakening from sleep at night because of oral dryness (Night-awake; never/1-2 per week/3-4 per week/5-6 per week/every night) Taking water to bed (H2O-bed; never/1-2 per week/3-4 per week/5-6 per week/every night) Sipping liquids to aid in swallowing dry foods (Sip-liq; never/occasionally/frequently/always) Using a candy or chewing gum due to oral dryness (Gum-candy; never/occasionally/frequently/always) Presence of dry mouth-associated complaints (yes/no) oral burning sensation, oral dysesthesia, taste disturbance, oral malodour, speaking difficulty</p>	X		X	X	X		X		X	X	X						different response options in each item	4	39, 617-619
<p>Xerostomia assessment by Torres et al Does your mouth feel dry when eating a meal? Do you have difficulties swallowing any foods? Do you need to sip liquids to aid in swallowing dry foods? Does the amount of saliva in your mouth seem to be reduced most of the time? Does your mouth feel dry at night or on awakening? Does your mouth feel dry during the daytime? Do you chew gum or use candy to relieve oral dryness? Do you usually wake up thirsty at night? Do you have problems in tasting food? Does your tongue burn?</p>	X			X		X		X	X								yes/no	3	620-622
<p>Xerostomia Inventory (XI) I sip liquids to aid in swallowing food My mouths feel dry when eating a meal I get up at night to drink My mouth feels dry I have difficulty in eating dry foods I suck sweets or cough lollies to relieve dry mouth I have difficulties swallowing certain foods The skin of my face feels dry My eyes feel dry My lips feel dry The inside of my nose feels dry</p>			X			X											1 - never 2 - hardly ever 3 - occasionally 4 - fairly often 5 - very often	68	40, 132, 182, 193, 195, 198, 205, 220, 266, 287, 288, 292, 300, 322, 324, 329, 331, 333, 351, 474, 476, 536, 543, 544, 551, 561, 569, 584, 597, 620, 621, 623-658
<p>Xerostomia Questionnaire by Dirix et al Part 1 grading of intensity of symptoms of xerostomia and related symptoms</p>	X					X			X	X							different response options in each item/part	5	237, 238, 309, 512, 659

<p>xerostomia: no xerostomia/now and then, partial/always, partial, completely dry, disturbing pain: no/seldom, minimal/always, strong/unbearable taste loss: no change/seldom, minimal/now and then, considerable/always dysphagia: no swallowing problems/solid food/soft food/liquid Part 2 quality of life Part 3 VAS for xerostomia</p>																		
<p>Xerostomia Questionnaire (XQ) by Eisbruch et al Rate your difficulty in talking due to dryness Rate your difficulty in chewing due to dryness Rate your difficulty in swallowing solid food due to dryness Rate the frequency of your sleeping problems due to dryness Rate your mouth or throat dryness when eating food Rate your mouth or throat dryness while not eating Rate the frequency of sipping liquids to aid swallowing food Rate the frequency of sipping liquids for oral comfort when not eating</p>		X					X		X						0-10	31	35, 45, 174, 215, 298, 305, 373, 386, 388, 407, 446, 457, 458, 509, 519, 525, 626, 642, 660-672	
<p>Ad hoc scales for the assessment of xerostomia</p>															different response options in each scale	68	10, 168, 224, 242, 252, 265, 286, 303, 394, 459, 471, 560, 564-566, 580, 661, 662, 673-724	

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