

Adult Oral Health Related Quality Of Life Instruments: A Systematic Review.

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Keywords:	Oral Health Related Quality of Life, Factor Analysis, Validity, Patient Reported Outcome Measures
Abstract:	To identify the existing OHRQoL instruments for adults, describe their scope (generic or specific), theoretical background, validation type, and cross-cultural adaptation. Methods: A systematic search was conducted and articles presenting validation of OHRQoL instruments in adults were included. Data were collected about the validation type: external validation (correlations/associations); or internal validation (Factor Analysis/Principal Components Analysis, Item Response Theory); and cross-cultural adaptation. Results: Of 3730 references identified, 326 were included reporting 392 studies. Forty-two original instruments were found among 74 different versions, 40 generic and 34 condition-specific. Locker's theoretical framework was the predominant model. The Oral Health Impact Profile (OHIP) presented 20 versions, with OHIP-14 being the most frequent (26.8%), followed by Geriatric Oral Assessment Index (GOHAI) (14.0%), OHIP-49 (11.7%) and Oral Impacts on Daily Performances (OIDP) (9.7%). Most studies focused on external validation (65.3%), while internal validation studies were conducted in English-speaking countries (n=23), and cross-cultural adaptation mostly in non-English-speaking European countries (n=40). Conclusions: Many generic and condition-specific instruments were found, but few have gone through a rigorous internal validation process or have undergone cross-cultural adaptation. This, in turn, makes it difficult for researchers to choose an appropriate measure based on known psychometric properties. OHIP-14, OIDP and GOHAI seem to be the most widely validated instruments. Equalising measurement properties for comparability is challenging due to theoretical heterogeneity. Future studies should assess psychometric properties, explore the factorial

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Adult Oral Health-Related Quality Of Life Instruments: A Systematic Review.

Running Head: OHRQoL Instruments: Systematic Review

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ABSTRACT

To identify the existing OHRQoL instruments for adults, describe their scope (generic or specific), theoretical background, validation type, and cross-cultural adaptation. Methods: A systematic search was conducted and articles presenting validation of OHRQoL instruments in adults were included. Data were collected about the validation type: external validation (correlations/associations); or internal validation (Factor Analysis/Principal Components Analysis, Item Response Theory); and cross-cultural adaptation. Results: Of 3730 references identified, 326 were included reporting 392 studies. Forty-two original instruments were found among 74 different versions, 40 generic and 34 condition-specific. Locker's theoretical framework was the predominant model. The Oral Health Impact Profile (OHIP) presented 20 versions, with OHIP-14 being the most frequent (26.8%), followed by Geriatric Oral Assessment Index (GOHAI) (14.0%), OHIP-49 (11.7%) and Oral Impacts on Daily Performances (OIDP) (9.7%). Most studies focused on external validation (65.3%), while internal validation was reported in 24.8% (n=26) of OHIP-14 studies, 50.9% (n=28) of GOHAI, and 21.1% (n=8) of OIDP studies. Most internal validation studies were conducted in English-speaking countries (n=33), and cross-cultural adaptation mostly in non-English-speaking European countries (n=40). Conclusions: Many generic and condition-specific instruments were found, but few have gone through a rigorous internal validation process or have undergone cross-cultural adaptation. This, in turn, makes it difficult for researchers to choose an appropriate measure based on known psychometric properties. OHIP-14, OIDP and GOHAI seem to be the most widely validated instruments. Equalising measurement properties for comparability is challenging due to theoretical heterogeneity. Future studies should assess psychometric properties, explore the factorial structure, and work towards a consensus on critical issues.

Keywords: Oral Health-Related Quality of Life, Factor Analysis, Validity, Patient-Reported Outcome Measures.

INTRODUCTION

Oral Health-Related Quality of Life (OHRQoL) studies date back to conceptual models in the early '80s^{1,2} - based on the International Classification of Impairments, Disabilities and Handicaps (ICIDH) - and have been growing fast since the mid-90s³. Locker et al. defined OHRQoL as the extent to which oral disorders affect functioning and psychosocial well-being¹. Similarly, the World Health Organization (WHO) defines Health-Related Quality of Life (HRQoL) as *"individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"*. It is a broad and complex concept influenced by a person's physical health, psychological state, level of independence, social relationships, personal beliefs, and relationship to salient features of their environment⁴.

Many measurement tools have been developed and validated to assess the degree of impact that oral health has on Quality of Life (QoL). Different from normative clinical measures, they include the subjective perceptions of individuals about their oral health. QoL instruments have been used in epidemiological surveys and clinical trials; guided health policies to incorporate patient-centred approaches, and assessed treatment needs^{5,6}. OHRQoL can be understood as a latent variable and, as such, can only be evaluated indirectly through composite measures⁷. Furthermore, it is a culturally sensitive concept, reflecting perceptions and norms that vary in different contexts⁸. Instruments, sometimes called measures or questionnaires, may be developed for specific age groups. Children, adults, and older adults have usually been focused on separately. Such measures may also be classified according to their scope, either generic or specific⁹.

The development of an instrument is a long process, and validating it is part of this process¹⁰. Initially, theoretical validation includes assessing the instrument concept and background, followed by face and content validation of proposed items. Then, internal validity assesses the dimensional structure of items, usually using factor analysis and related techniques in addition to commonly used internal consistency indicators (e.g., Cronbach's alpha). Finally, external validity is assessed with constructs theoretically related to the instrument, based on a strong *a priori* hypothesis

about how they covary, with the purpose to assess whether the instrument measures what is intended from a conceptual stance.

OHRQoL instruments have been extensively used in dental research to assess the impact of different oral conditions on daily life, beyond the setting in which they were initially developed. When an instrument requires use in a different culture, it needs to undergo a rigorous cross-cultural adaptation process¹¹,¹².

To date, to the best of the authors' knowledge, there is no systematic review of OHRQoL instruments, much less concerning their respective developmental histories, be them theoretical or empirical. Such information would help researchers in selecting the most appropriate one in a specific setting and context. Therefore, this study aimed to identify the existing OHRQoL instruments for adults and describe their scope (generic or specific), theoretical background, validation type, and cross-cultural adaptation. SCIN

METHOD

Two research questions were addressed: "Which are the available oral health-related quality of life instruments for the adult population?" and "Which validation methods have been mostly used?" A search strategy was developed combining two groups of strings: 1) OHRQoL terms and 2) a high-sensitivity filter to retrieve validation studies proposed by the COSMIN initiative¹³. This strategy was developed using PubMed controlled vocabulary (MeSH terms) and then adapted for Scopus (see supplemental file). To include grey literature, a Google Scholar search was run, and references of two books^{9,14}, two previous revisions^{15,16}, and included articles were scrutinised to detect additional papers not retrieved in the search. In addition, authors of identified instruments were contacted by e-mail if further information was needed.

Selection criteria

Articles assessing psychometric properties of OHRQoL instruments in the adult population were included without language or year limits until April 2021, the review is registered in Prospero (CRD42018110341). Psychometric information was also

extracted from studies in which the primary purpose was not the validation of an OHRQoL instrument but presented results about it. We excluded studies during any selection step: a) in which the whole sample was under 18 years old; b) that did not include psychometric analysis; c) not involving a QoL instrument; and d) that were review, animal, or laboratory articles. Instruments with fewer than three items were dropped¹⁷.

Data extraction and study variables

Once potential studies were identified, two researchers (FR and MCS) read all the titles and abstracts, if there was insufficient information for a decision, the article was selected for full text reading. In case of disagreement, a third author (RKC or GS) was consulted, but only 45 cases remained unclear out of 3730 titles/abstracts screened. Subsequently, the following information was extracted on the: (i) development of the instrument (original instrument or a new version); (ii) scope of the instrument (generic oral health or condition-specific); (iii) main psychometric properties assessed (external or internal validation); and (iv) whether or not the study involved a cross-cultural adaptation process. In this regard, the eligibility criteria were if the authors explicitly mentioned cross-cultural adaptation as the study aim or if a pre-established guideline or necessary steps for a translation was employed. If the background of the instrument was not clear, the original reference was consulted. Also, the following information was sought: (i) first author; (ii) journal of publication; (iii) year of publication; (iv) country of the study; (v) on whether validation of the OHRQoL instrument was one of the objectives; (vi) instrument name; (vii) the number of items; (viii) aim of the instrument when developed; (ix) type of validation performed; and (x) data on the process of cross-cultural adaptation.

Several psychometric properties were reported in the included studies, and nonexclusive categories were created based on available information. We classified as addressing internal validation if an article reported results from a Principal Component Analysis, an Exploratory or Confirmatory Factor Analysis; an Item Response Theory model; or a Structural Equation Model. External validation was considered when any association was identified between the instrument and another construct.

RESULTS

The initial search identified 3730 references. Reading titles and abstracts excluded 3340 publications not fulfilling the eligibility criteria. The remaining 390 articles were read in full, 64 of which were subsequently excluded according to the specified eligibility criteria. As this study objective was to describe the process of instrument validation, and many articles covered more than one at a time and sometimes in different populations, the selected 326 articles effectively covered 392 validation studies (Figure 1).

Based on the data, the selected instruments were then classified into five features, namely, (i) name and the number of items; (ii) year of publication (1990- 2000, 2001- 2005, 2006-2010, 2011-2015, and 2016-2021); (iii) journal of publication; (iv) language and country or group of countries of publication (a single country, group of countries, or multi-country according to cultural and language similarities); and (v) validation as an objective (yes or no).

Characteristics of the studies and the retrieved instruments

A total of 74 OHRQoL instruments were identified, all derived from 42 original versions. Regarding their aims, 40 were generic (18 original versions), and 34 were conditionspecific OHRQoL guestionnaires (24 original versions, 9 OHIP versions and 1 derived versions), the most frequent among the latter being aesthetic-, prosthetic-, and surgical-related instruments (Table 1). Their theoretical model was often difficult to establish because it was usually not explicitly specified^{1,18_21}. Locker's framework was the most widely used, with four generic instruments (Oral Health Impact Profile - OHIP, Oral Impact on Daily Performances - OIDP, Geriatric Oral Assessment Index - GOHAI, Subjective Oral Health Status Indicators - SOHSI) and nine specific ones (OHIP-Temporomandibular disorders [two instruments], OHIP-Masticatory efficiency, OHIP-Edentulism, OHIP-Aesthetic, OHIP-Prosthodontics, **OHIP-Periodontitis Itwo** instruments], OPMDQoL [Oral Potentially Malignant Disorders]) (Figure S1 and Table 1)<mark>.</mark>

The OHIP presented the highest number of variants with 20 versions. The instrument was also the most frequently validated; there were 105 validation studies (26.8%)

about OHIP-14 and 46 (11.7%) about OHIP-49. The second most frequently assessed measurement tool was the GOHAI, with 55 studies (14.0%), followed by the OIDP with 38 studies (9.7%) (Table S1).

The group of journals with the highest number of publications were *Dental Journals*, with 50.8% (Table S1). The number of publications has continuously been increasing over time, peaking in the 2011-2015 period with 32.4% of the cases. The majority of the studies were from English-speaking countries (USA, UK, Canada, Ireland, Australia, New Zealand) with 25.6%; while other European countries represented 18.4%, and Brazil-Portuguese was the second-highest single-language group (8.9%) (Table S1).

Type of validation

A larger number of studies carried out external (65.3%) over internal validation (34.7%). The GOHAI was the only single instrument subjected to more internal than external validation. Internal validation was reported in 24.8% (n=26) of the OHIP-14 studies, 21.1% of the OIDP (n=8) studies, and in 50.9% (n=28) of the GOHAI studies (Table S1).

The number of internal validation studies has been increasing over the years, peaking in the 2016-2021 period (n=44), but external validity was more frequent than internal validation in all periods (Table S1). Regarding the journals of publication, all groups presented some form of external validity as the most common method of validation, and *Dental Journals* had the highest number of both internal (n=67) and external (n=132) validity studies (Table S1). Differences were found regarding the target populations for internal validation (Table S1), the English-speaking countries having most studies (n=33) followed by Brazil (n=15).

Cross-cultural adaptation

Cross-cultural adaptation was reported in 99 studies (Table S1), 25.3% of all studies. GOHAI presented the highest percentage (34.6%) among all instruments. Cross-cultural adaptation studies comprised 8.3% of validation studies in 1990-2000, increasing over time with the highest percentage in 2015-2021 with 35.6%. The

 category of non-English-speaking European countries (Scandinavian, Germany/Netherlands and all others) had the highest number of studies (n=40). Because most instruments were developed in English, English-speaking countries presented only one cross-cultural validation study each (Table S1).

DISCUSSION

This review compiled all currently available OHRQoL instruments and described their theoretical background and the type of validation they have undergone so far. A variety of theoretical models were described, and the most frequent was Locker's framework. Internal validation was performed in 34.7% of the studies, and 25.3% published some kind of cross-cultural adaptation. The number of internal validation studies was low in the early periods, showing that this methodology was not popular during the development of current generic instruments²²,²³. Nevertheless, there were many external validation studies, which is an essential aspect for a comprehensive evaluation of their scope and performance.

Some limitations should be highlighted. This review should not imply that any instrument is better validated than the others or that any instrument is fully validated because it was tested in several studies. This issue is an important point since only the number of validation studies was addressed, without detailing the psychometric properties and related statistical methods. For example, some studies reported that several factors (domains) emerged from factor analysis of OHIP-14, while others reported only one factor²⁴,²⁵.

Several well-known instruments have already undergone internal and external validation process²⁴—²⁹. For a start, the number of factors in an instrument should mirror its theoretical dimensions; nonetheless, a rapid assessment shows a plethora of different factorial solutions for the same instruments²⁴—²⁶,³⁰—³⁴. It is unclear if this is due to the different methodological approach. For example, whilst most studies use classical theory (e.g., factor analysis), one study was found assessing the performance over the latent trait score, using item response theory³⁵.

A larger number of instruments (n=42) were identified in the current study than in previous ones (n=14 and n=17)^{15,16}. Probably, this reflects the rising tendency to use condition-specific instruments (most of them developed in the last decade), together with the demand for shorter and easily applicable versions³⁶ for large surveys. Many condition-specific instruments were found, and some authors suggested their use in addition to generic ones to address clinically relevant factors²³. It should be noted that many specific instruments are derived from generic ones; therefore, some overlap is likely to exist either in background theory, items, and/or purpose. Our decision to classify as generic/specific was based on the authors' recommendations, but additional assessment of their properties is warranted.

In the current study, an attempt was made to understand the relationship between the instruments and their theoretical models (Figure S1). A recent scoping review found nine models used in OHRQoL research³⁷, however it was not clear how much those models were used for instrument development. Ideally, such development should start from a theoretical model towards the generation of items, but this process is not always clear. Sometimes, an instrument concept and dimensional structure are refined and clarified after exploratory analysis. This aspect is evident in Table 1, where only a few studies explicitly stated their specific theoretical models²,³⁸–⁴². The most frequent is the Locker's model, which is based on ICIDH, superseded by the International Classification of Functioning, Disability and Health (ICF)⁹. The former model follows from disease to impairment; however, given a shift towards health and function has been advocated, current instruments should be assessed under new theoretical models⁹.

Factor analysis provides information for internal validity by testing a postulated model (dimensional structure) to evaluate whether it explains the observed data⁷. The present work identified fewer publications addressing internal validation than external validation, perhaps because researchers in the field are used to the latter type of studies. Although factor analysis is not a new method, internal validation studies were relatively scarce in the first analysed periods (1990-2000 and 2001-2005). Interpreting OHRQoL scores are very important⁴³, and factor analysis studies²⁴–²⁶,²⁸,²⁹ can help in this matter, refining scale properties and comparing results in different cultures, promoting understanding of the underlying constructs that the instruments cover.

Since OHRQoL is a culturally and dynamically defined concept⁴⁴, more cross-cultural adaptations are desirable in different socio-cultural and linguistic domains and across periods. Perceptions about what constitutes quality of life may change over time⁴⁵. A relatively small number of cross-cultural adaptations assessing psychometric properties may also be an issue⁴⁶. However, some studies may not have required cross-cultural adaptation because we could not define when each instrument was used in a setting different from where it was initially developed. Therefore, the percentage of cross-cultural adaptations reported here should not be interpreted as low or high. A key aspect for further analysis will be to investigate when those instruments were used for the first time in a new setting/culture and assess in more detail the adaptation process.

Instruments described here have been applied in countries with languages and cultures different from the original versions. The target population is an important aspect to consider with assessing the validity of a measure, and a universalist approach has usually been adopted in the course of cross-cultural adaptation^{11,12,47}. Accordingly, qualitative studies could be considered part of the theoretical equivalence process and contribute to incorporating cultural differences in the item pool. Unfortunately, this has been scarcely reported in our findings.

In conclusion, the present study is a step towards a more comprehensive analysis of OHRQoL instruments and their theoretical background. The historical and current high number of instruments offers a broad range of measurement options for different settings. However, few have gone through a rigorous internal validation process or cross-cultural adaptation, making it difficult for researchers to choose based on psychometric properties. Although instruments are conceptually different, they may have good psychometric properties; While OHIP-14, OIDP and GOHAI seem to be the most widely validated instruments, their specific psychometric properties need to be scrutinized. Equalising the measurement properties, and therefore allowing comparisons may be challenging because of the lack of theoretical comparability. Perhaps, instead of improving any specific instrument, work towards an international consensus on oral health quality of life measures may help achieve agreement on critical issues.

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Table 1 – Retrieved OHRQoL instruments and aim (References available in Table S2)

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3	Instrument	Items	Concept (explicit in	Proposed Dimensions	Origin	Languages -
4	name	(versions)	development article)	(explicit in development article)	oritems	Countries
5				GENERIC INSTRUMENTS		
7	SIDD - Social Impacts of Dental Disease	14	Bio-psycho-social model applied to dental illness	5 - Functional, Social interaction, Comfort and wellbeing, Self-image	Qualitative interviews	English - England
8 9	GOHAI - Geriatric Oral Health Assessment Index	12	Locker's conceptual model (Not explicitly stated)	3 - Physical function, psychosocial function, Pain or discomfort	Literature review, consult with health care providers and patients, qualitative research	English - USA
10 11	DIP - Dental Impact Profile	25	Not explicitly stated	4* - Eating, Health/Well-being, Social relations, Romance	Qualitative interviews Pre-test on elderly and college age respondents	English - USA
12 13 14	OHIP - Oral Health Impact Profile	49 (14, 55, 54, 46, 45, 22, 7, 7, 5, 12sign leng.)	Locker's conceptual model	7 - Functional limitation, Physical pain, Psychological discomfort, Physical disability, Psychological disability, Social disability, Handicap	Interviews using open ended questions including adaptation of an existing inventory for handicap dimension	English - Australia
15 16 17	SOHSI - Subjective Oral Health Status Indicators	42	Locker's conceptual model	8 - Ability to chew, Ability to speak, Oral and facial pain symptoms, Other oral symptoms, Eating, Communication/social relations, Activities of daily living, Worry/concern.	Developed ad hoc over a series of studies comprised by preexisting indexes and scales	English - Canada
18 19	DIDL - Dental Impact on Daily Living	36 (49, 33)	Not explicitly stated.	5* - Comfort, Appearance, Pain, Performance, Eating	Open interviews, literature review and items in SIDD	English, Portuguese - England, Brazil
20	OHQOL - Oral Health Related Quality of Life Measure	3 (8)	Not explicitly stated.	1* - OHRQoL	From existing instruments	English - USA
22	OIDP - Oral Impact on Daily Performances	8 (7, 9, 10, 11, 12)	Last level of impact in Locker's conceptual model	3 - Physical, Psychological, Social	Qualitative research including existing sociodental and sociomedical measures	English, Thai - Thailand
23 24	OH-QoL - Oral Health Quality of Life Inventory	15	Not explicitly stated.	2 - Importance, Satisfaction	Synthesis of the literature and expert judgment	English - USA
25 26	ICSII-OHRQOL - Intern. Collaborative St. on Oral Health Care Systems	15	Not explicitly stated.	3 - Dental symptoms, Perceived oral well-being, Oral functioning	Not explicitly stated	English, Polish, German - New Zealand, Poland, Germany
27	Rand Health Insurance St.	3	Not explicitly stated.	1 - (Not specified)	Adapted from items of health measures	English - USA
28 29 30	Gadbury-Amyot 1999 - OHRQOL for Dental Hygiene	50	including symptom status, functional status, and oral health perceptions	3 - Symptom status, Functional status, Oral health perception	dentistry, medicine, nursing, and physical therapy	English - USA
31	OHQoL-UK - Oral Health Quality of Life - UK	16	Not explicitly stated.	1* - Unnamed	Open ended interviews	English - UK
32 33	FIS - Family Impact Scale	14 (8, 19)	Not explicitly stated.	3* - Parental/family activity, Parental emotions, Family conflicts	Review of existing OHRQoL instruments and qualitative interview	English - Toronto
34 35	LORQ (v1-v3) - Liverpool Oral Rehabilitation Quest.	V1 - 25 V3 - 40	Not explicitly stated.	V1 - 2 - Oral function, Denture satisfaction V3 - 4 - Adds Oro-facial appearance, Social interaction	Clinical experience and review of existing instruments	English - England
36 37	OQOL - Oral Quality Of Life	12 (6)	Framework adapted from various models. Concept not explicitly stated.	4 - Physical function, Psychosocial functioning, Impairment or disease, Perceptions	Items from OHIP, GOHAI and OHQOL	English - USA
38 39 40	POHW - Positive Oral Health and Wellbeing	17	Positive oral health attributes and perceptions, may result, via appropriate oral health behavior, on positive oral health	2* - Good feelings, Positive impact	Expert's judgement	English, German, and Hebrew - USA, Germany, Israel
41 42 43	OHIDL - Oral Health Impact on Daily Life	20	Concept not explicitly stated. Qualitative approach to subjects' values of importance.	8* - Cleaning, Eating, Speaking, Appearance, Social, Psychological, Health, Finance	Semi-structured interviews to patients of the target population (Chinese elders)	Chinese - China
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1				SPECIFIC INSTRUMENTS		
2 3	OHIP-30TMD - OHIP for Temporo-mandibular disorders	30	Based on OHIP (Locker's model)	6 - Functional limitation, Psychological discomfort, Physical disability, Psychological disability, Social disability, Handicap	Items from OHIP and specific TMD-Pain items from unspecified source	English - Canada
4 5 6	Savin1997 - QoL after removing of impacted lower wisdom	11	Not explicitly stated.	5 - Eating, Speech, Physical effect, Appearance, Other aspects of treatment	Expert's judgement	English - UK
7 8	OQLQ - Orthognathic Quality of Life Questionnaire	22	Not explicitly stated.	4* - Social aspect of deformity, Facial aesthetics, Function, Awareness of facial deformity	Literature review and interviews with health professionals and patients.	English - UK
9	XeQoLS	15	Not explicitly stated	 4 - Physical functioning, Personal/psychological functioning, Social functioning, Pain/discomfort issues 	Not explicitly stated	English - USA
10 11	Okamoto et al - QoL in patient with fixed prosthesis**	(16 - 18)	Not explicitly stated.	5 - Mastication and oral pain, Pronunciation, Swallowing, Oral cleaning, Aesthetic	Items from OHIP	Japanese - Japan
12 13	OHIP-EDENT - OHIP for edentulous patients	19 (20)	Based on OHIP (Locker's model)	7 - Functional limitation, Physical pain, Psychological discomfort, Physical disability, Psychological disability, Social disability, Handicap	Items from OHIP selected by item impact method	English - Canada, UK
14 15 16	LDF-TMDQ - Limitations of daily function-TMD questionnaire	10	Not explicitly stated.	3* - Limitation in executing a certain task, Limitation of mouth opening, Limitation of sleeping	Previous clinical research and patients' feedback	Japanese - Japan
17	Manchester Orofacial Pain Disability Scale	32	Not explicitly stated.	2 - Physical, Psychological	Patients interview, and expert's judgement	English - UK
19	PIDAQ -Psychosocial Impact of Dental Aesthetics Quest.	23	Not explicitly stated.	4* - Dental self-confidence, Social impact, Psychological impact, Aesthetic concern	Items from OQLQ, literature review, and expert's judgement	Not clear in development article
20 21	MHISS - Mouth Handicap is Systemic Sclerosis scale	12	Not explicitly stated.	3* - Restriction in mouth opening, Mouth dryness, Aesthetic concerns	Patients interview, literature review of scales concerning the mouth, and expert's judgement	French - France
22 23	OHIP Aesthetic - OHIP for dental aesthetics	14	Based on OHIP (Locker's model)	7 - Functional limitation, Physical pain, Psychological discomfort, Physical disability, Psychological disability, Social disability, Handicap	Items from OHIP selected by stepwise procedure after FA	Chinese - China (Hong Kong)
24 25 26 27	SOOQ - Surgical Orthodontic Outcome Questionnaire	33	Not explicitly stated.	5 - Issues before surgery, Issues after surgery, Dental aesthetics, Facial aesthetics, Emotional and social well-being	Reviews of the literature on motivations for treatment, reviews of existing OHRQoL measures, (OHIP, COHQoL, OQLQ), and expert clinical opinion	English - Canada
28 29 30	OES - Oral Esthetic Scale	8	Unidimensional Construct reflecting patients perceived esthetic values, measuring the direct or primary esthetic impacts.	1* - Aesthetics	Patients interviews, focus group of dental professionals, pre-test group	Swedish - Sweden
31 32 33	DHEQ - Dentine Hypersensitivity Experience Questionnaire	48	Relationship between clinical status, symptoms, functioning, perceived health and overall quality of life	8 - Pain, Functional restrictions, Adaptation, Avoidance, Social impact, Emotional impact, Identity, Effect on life overall	Qualitative interviews	English - Canada
34 35	PQL - Prosthetic quality of life	11	Not explicitly stated.	3* - Physical well-being, Psychological well-being, Social well-being	Qualitative interviews and expert's panel based on studies assessing OHRQoL of patients with removable prothesis	Spanish - Spain
36 37 38	OHIP-22TMD - OHIP for Temporo-mandibular disorders	22	Based on OHIP (Locker's model)	7 - Functional limitation, Physical pain, Psychological discomfort, Physical disability, Psychological disability, Social disability, Handicap	Items from OHIP selected by a mixed quantitative and qualitative method	English - UK
39 40	COMDQ - Chronic Oral Mucosal Diseases Questionnaire	26	Not explicitly stated.	4 - Pain and functional limitations, Medication and treatment, Social and emotional, Patient support	Literature review, expert's judgement, and qualitative interviews (focus group)	English - Irland
41 42	HALT - Halitosis Associated Life-quality Test	20	Not explicitly stated.	Unspecified	Modified Items from SF-36, OHIP-14, OQLQ. Patient interviews	English - USA
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1	Musurlieva 2012 - Impact of Periodontal diseases	9	Not explicitly stated.	3 - Choice of food/nutrition chewing swallowing talking, Social relations, Overall health	Not specified	Bulgarian - Bulgaria
2 3	OHIP-13-POST OHIP for post prosthetic treatment	13	Based on OHIP (Locker's model)	7 - Functional limitation, Physical pain, Psychological discomfort, Physical disability, Psychological disability, Social disability, Handicap	Items from OHIP-EDENT	Spanish - Spain
4 5 6 7	EORTC QLQ-OH17 - European Org. for Research and Treat. of Cancer QoL Quest. Oral supplement	17	Not explicitly stated.	4 - Pain/discomfort, Xerostomia, Eating, Information. And three single items related to use of dentures and future worries	Literature review, semi-structured interview to healthcare professionals and patients	English, Dutch, Swedish, French, German, Greek, Hebrew, Norwegian - Europe
8	QoLIP-10 - Quality of Life with Implant-Prostheses	10	Not explicitly stated.	3 - Biopsychosocial dimension, Dental-facial aesthetics dimension. Performance dimension	Literature review, experts' judgment, patients' interviews	Spanish - Spain
9 10	OHIP-7-ME - OHIP for Masticatory efficiency	7	Based on OHIP (Locker's model)	Unspecified	Items from OHIP about perceived masticatory efficiency and a clinical test	French, English - Canada
11 12	QoLDAS-9 - Quality of Life associated with Dental Aesthetics Satisfaction	9	Not explicitly stated.	3* - Psycho-facial aesthetics, Interactive aesthetics, Socio-dental aesthetics.	Literature review, expert's judgment, patients' interviews and focus groups	Spanish - Spain
13 14	TOQOL - Teen Oral Health Quality of Life***	16	Gift and Atchinson's conceptualization	5 - Physical functioning, Role functioning, Social functioning, Oral problems, Emotional functioning	Literature review, Focus group interviews, Experts' judgment, Factor analysis	English - USA
15 16	OPMDQoL - Oral Potentially Malignant Disorders QoL	20	Modified from the OIDP theoretical framework (Locker's model)	4* - Difficulties with diagnosis, Physical impairment and functional limitations, Psychological and social wellbeing, Effect of treatment on daily life	Qualitative data and review of existing questionnaires	Telugu, English - India
17 18 19	OHIP-CP - OHIP for Chronic Periodontitis	18	Based on OHIP (Locker's model)	3 - Pain and functional limitation, Psychological discomfort, Psychological disability and social handicap	OHIP-49, focus groups with patients and expert's panel	Chinese - China
20 21 22	OHIP-14-PD - OHIP-14 for Periodontal Disease	14	Based on OHIP (Locker's model)	7 - Functional limitation, Physical pain, Psychological discomfort, Physical disability, Psychological disability, Social disability, Handicap	Adapted from OHIP-14 based on the Periodontal Disease Classification System of the American Academy of Periodontology and information provided by patients	Spanish - Mexico
23 24 25	OHRQoL-OSF - Oral Health Related Quality of Life-Oral Submucous Fibrosis	17	Not explicitly stated.	 4 - Discomfort and functional impairment, Psychological wellness, Physical wellness, Social wellness 	Focus group interviews, personal interviews, and expert's judgment	English - India
26	SCOOHP - Schizophrenia Coping Oral Health Profile	23	Not explicitly stated	Unspecified	Semi-structured interviews	English. French - France
27 28 29	CCU-OHQoL - Critical Care Units Oral Health-related Quality of Life	15	Not explicitly stated.	5* - Satisfaction with oral health, Functional limitations, Self-care, Psychological impact, Xerostomia	Literature review and Panel of experts	English - UK
30 31	Mijiritsky 2020 - Impact of prosthetic treatments on OHRQoL	31	Not explicitly stated.	6 - Functional disability, Physiological pain, Psychological discomfort, Physiological disability, Psychological disability, Social disability	Questions from the OHIP-49 and PIDAQ	English - Israel
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• * FA into the development of the scale for evaluation and/or identification of factors.

• ** Instrument with unclear origin, information obtained from various articles.

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44 45 46 • *** Generic instrument for teenagers validated and used as a specific orthodontic instrument in adults.

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				T	ype of Va	lidation		Cros	s-cultu	ral adaptat	tion
		Tot	tal	Exter	nal	Interi	nal	Yes	3	No	
		%	n	%	n	%	n	%	n	%	n
	Total	100,0	392	65,3	256	34,7	136	25,3	99	74,7	293
Validation was the	yes	77,6	304	63,2	192	36,8	112	31,9	97	68,1	201
primary objective	no	22,5	88	72,7	64	27,3	24	2,3	2	97,7	86
	1990-2000	6,1	24	58,3	14	41,7	10	8,3	2	91,7	22
	2001-2005	13,0	51	78,4	40	21,6	11	17,7	9	82,4	42
Year of publication	2006-2010	21,9	86	59,3	51	40,7	35	22,1	19	77,9	67
	2011-2015	32,4	127	71,7	91	28,4	36	25,2	32	74,8	95
	2016-2021	26,5	104	57,7	60	42,3	44	35,6	37	64,4	67
	Dental Journals	50,8	199	66,3	132	33,7	67	27,1	54	72,9	145
Iournals of Publication	Dental Public Health	20,7	81	65,4	53	34,6	28	12,4	10	87,7	71
	Non-dental Journals	19,4	76	65,8	50	34,2	26	36,8	28	63,2	48
	Quality of Life	9,2	36	58,3	21	41,7	15	19,4	7	80,6	29
	USA, UK, Canada, Ireland	23,0	90	67,8	61	32,2	29	1,1	1	98,9	89
	Other European	18,4	72	59,7	43	40,3	29	38,9	28	61,1	44
	Brazil	8,9	35	57,1	20	42,9	15	20,0	7	80,0	28
	Middle East	8,2	32	56,3	18	43,8	14	43,8	14	56,3	18
	Germany/The Netherlands	7,1	28	75,0	21	25,0	7	17,9	5	82,1	23
	India	5,9	23	82,6	19	17,4	4	39,1	9	60,9	14
Country	China	4,6	18	44,4	8	55,6	10	44,4	8	55,6	10
,	Scandinavian	4,6	18	72,2	13	27,8	5	38,9	7	61,1	11
	Other Asian	4,3	17	76,5	13	23,5	4	41,2	7	58,8	10
	Japan	4,1	16	75,0	12	25,0	4	12,5	2	87,5	14
	Other Latin America	3,6	14	64,3	9	35,7	5	42,9	6	57,1	8
	African Countries	2.8	11	90,9	10	9,1	1	27,3	3	72,7	8
	Australia, New Zealand	2,6	10	60,0	6	40,0	4	0.0	0	100.0	10
	Multi countries	2,0	8	37,5	3	62,5	5	25.0	2	75,0	6
	OHIP-14	26,8	105	75,2	79	24,8	26	18,1	19	81,9	86
	OHIP-49	11,7	46	84,8	39	15,2	7	19,6	9	80,4	37
	Other OHIP	12.0	47	59.6	28	40,4	19	19.2	9	80.9	38
Instrument (measure)	GOHAI-12	14.0	55	49.1	27	50.9	28	34.6	19	65.5	36
	OIDP	9,7	38	79,0	30	21,1	8	26,3	10	73,7	28
	Other Generics	8.4	33	66.7	22	33.3	11	21.2	7	78.8	26
	Condition Specific	17.4	68	45.6	31	54.4	37	38.2	26	61.8	42

TABLE S1- Frequency studies according to validation type used and the presence of cross-cultural adaptation.

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FIGURE S1 - Record of the development of the original versions of the existing generic instruments and their relationship with the conceptual model or theoretical background.



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DIP	Strauss RP, Hunt RJ. Understanding the value of teeth to older adults: influences on the quality of life. <i>J Am Dent Assoc.</i> 1993;124:105–10.
ОНІР	Slade GD, Spencer AJ. Development and evaluation of the Oral Health Impact Profile. <i>Community Dent Health.</i> 1994;11:3–11.
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DIDL	Leao A, Sheiham A. The development of a socio-dental measure of dental impacts on daily living. <i>Community Dent Health</i> . 1996;13:22–6.
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OHIP-CP	He S, Wang J, Wei S, Ji P. Development and validation of a condition-specific measure for chronic periodontitis: Oral health impact profile for chronic periodontitis. J Clin Periodontol. Blackwell Munksgaard; 2017;44:591–600.
OHIP-14-PD	Rodríguez NI, Moral J. Adaptation and content validity by expert judgment of the oral health impact profile applied to periodontal disease. <i>J Oral Res.</i> 2017;6:92–6.
OHRQoL-OSF	Gondivkar S, Bhowate R, Gadbail A, Gaikwad R, Gondivkar R, Sarode S, et al. Development and validation of oral health-related quality of life measure in oral submucous fibrosis. <i>Oral Dis.</i> 2018;24:1020–8.
SCOOHP	Siu-Paredes F, Rude N, Rat C, Reynaud M, Hamad M, Moussa-Badran S, et al. The schizophrenia coping oral health profile. Development and feasibility. <i>Transl Neurosci.</i> 2018;9:78–87.
CCU-OHQoL	Moreno Sancho F, Tsakos G, Brealey D, Boniface D, Needleman I. Development of a tool to assess oral health-related quality of life in patients hospitalised in critical care. <i>Qual life Res.</i> 2020;29:559–68.
Mijiritsky 2020	Mijiritsky E, Lerman Y, Mijiritsky O, Shely A, Meyerson J, Shacham M. Development and validation of a questionnaire evaluating the impact of prosthetic dental treatments on patients' oral health quality of life: A prospective pilot study. <i>Int J</i> <i>Environ Res Public Health</i> . 2020;17:1–19.

TABLE S3 - PRISMA CHECKLIST

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
Rationale	3	Describe the rationale for the review in the context of what is already known.	4 (par3)
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4 (par3)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	4 (par5)
PEligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4 (par4)
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4 (par4)
7 Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1 and 2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5 (par 2)
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5 (par 2, 3)
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5 (par 2, 3)
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	not applicable
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	not applicable
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.	not applicable

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Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	not applicable
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	not applicable
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6 (par 1)
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6 (par 2)
5 Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	not applicable
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	not applicable
9 Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	not applicable
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	not applicable
2 Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Pag 7 (Table S1)
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	Table 1
8 Limitations 9	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	8 (par 3)
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	10 (par 3)
4 Funding 5	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	11
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APPENDIX 1 - PUBMED SEARCH STRATEGY

(((((("aged"[MeSH Terms] OR "middle aged"[MeSH Terms] OR "of age"[Title/Abstract]) NOT "adolescent"[Title/Abstract]) NOT "children"[Title/Abstract]) NOT "child"[Title/Abstract]) NOT "child, preschool"[MeSH Terms]) NOT "infan"[Title/Abstract]) NOT "gestation"[Title/Abstract]) NOT "neonatal"[Title/Abstract]) AND (("oral health related quality of life"[Title/Abstract] OR "ohip*"[Title/Abstract] OR "oral health impact profile"[Title/Abstract] OR "oidp*"[Title/Abstract] OR "oral impact on daily performance"[Title/Abstract] OR "oral impact on daily performances"[Title/Abstract] OR "oral impacts on daily performance index"[Title/Abstract] OR "oral impacts on daily performances"[Title/Abstract] OR "gohai*"[Title/Abstract] OR "general oral health assessment index"[Title/Abstract] OR "geriatric oral health assessment"[Title/Abstract] OR "ecohis"[Title/Abstract] OR "early childhood oral health impact scale"[Title/Abstract] OR "cohip"[Title/Abstract] OR "child oral health impact profile"[Title/Abstract] OR "didl"[Title/Abstract] OR "dental impact on daily living"[Title/Abstract] OR "sidd"[Title/Abstract] OR "ohgol uk"[Title/Abstract] OR "dip"[Title/Abstract] OR "pohw"[Title/Abstract] OR "oqlq"[Title/Abstract] OR "miq"[Title/Abstract] OR "fis"[Title/Abstract] OR "family impact scale"[Title/Abstract] OR "golip 10"[Title/Abstract] OR "guality of life with implant prostheses golip 10"[Title/Abstract]) AND ("instrumentation"[MeSH Subheading] OR "methods" [MeSH Subheading] OR "comparative study" [Publication] Type] OR "psychometrics"[MeSH Terms] OR ("psychometrc"[Title/Abstract] OR "psychometri"[Title/Abstract] OR "psychometric"[Title/Abstract] OR "psychometric"[Title/Abstract] OR "psychometrica"[Title/Abstract] OR "psychometrical"[Title/Abstract] OR "psychometrically"[Title/Abstract] OR "psychometrically"[Title/Abstract] OR "psychometricallydefined"[Title/Abstract] OR "psychometrican"[Title/Abstract] OR "psychometricevaluation"[Title/Abstract] OR "psychometrician"[Title/Abstract] OR "psychometricians"[Title/Abstract] OR "psychometricians"[Title/Abstract] OR "psychometricly"[Title/Abstract] OR "psychometricproperties"[Title/Abstract] OR "psychometrics"[Title/Abstract] OR "psychometrics"[Title/Abstract] OR "psychometrie"[Title/Abstract] OR "psychometries"[Title/Abstract] OR "psychometrika"[Title/Abstract] OR "psychometrique"[Title/Abstract] OR "psychometriques"[Title/Abstract] OR "psychometris"[Title/Abstract] OR "psychometrische"[Title/Abstract] OR "psychometrist"[Title/Abstract] OR "psychometrists"[Title/Abstract] OR "psychometry"[Title/Abstract]) OR ("clinimetria"[Text Word] OR "clinimetric"[Text Word] OR "clinimetric" [Text Word] OR "clinimetrical" [Text Word] OR "clinimetrically"[Text Word] OR "clinimetrically"[Text Word] OR "clinimetrician"[Text Word] OR "clinimetrics"[Text Word] OR "clinimetrics"[Text Word] OR "clinimetrie"[Text Word] OR "clinimetry"[Text Word]) OR ("clinometric"[Text Word] OR "clinometrically" [Text Word] OR "clinometrics" [Text Word] OR "clinometry" [Text Word]) OR "outcome assessment"[Title/Abstract] OR ("outcome measure"[Text Word] OR "outcome measured" [Text Word] OR "outcome measurement" [Text Word] OR "outcome measurements" [Text Word] OR "outcome measurers" [Text Word] OR "outcome measures"[Text Word] OR "outcome measuresnumber"[Text Word] OR "outcome measureswe"[Text Word]) OR "observer variation"[MeSH Terms] OR "observer variation"[Title/Abstract] OR "health status indicators"[MeSH Terms] OR

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41	"reliablegeneme"[Title/Abstract] OD "reliableron [Title/Abstract] OD
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43	reliableness [Title/Abstract] OR reliablenesses [Title/Abstract] OR
44 45	"reliableoutcome"[Title/Abstract] OR "reliablereporters"[Title/Abstract] OR
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47	"reliablethe"[Title/Abstract] OR "reliablility"[Title/Abstract] OR
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50	"reliaby"[Title/Abstract]) AND ("test"[Title/Abstract] OP "retest"[Title/Abstract])) OP
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55 56	"intratester"[Title/Abstract] OR "intra tester"[Title/Abstract] OR
50	"interobserver"[Title/Abstract] OR "inter observer"[Title/Abstract] OR
58	"intraobserver"[Title/Abstract] OR "intra observer"[Title/Abstract] OR
59	"intertechnician"[Title/Abstract] OR "inter technician"[Title/Abstract] OP
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APPENDIX 2 - SCOPUS SEARCH STRATEGY

(TITLE-ABS-KEY (aged OR age OR adult OR "Middle aged" OR "of age")) AND

(TITLE-ABS-KEY ("oral health related quality of life" OR "ohip*" OR "oral health impact profile" OR "oidp*" OR "oral impact on daily performance" OR "oral impact on daily performances" OR "oral impacts on daily performance index" OR "oral impacts on daily performances" OR "gohai*" OR "general oral health assessment index" OR "geriatric oral health assessment" OR "didl" OR "dental impact on daily living" OR "sidd" OR "ohqoluk" OR "dip" OR "pohw" OR "oqlq" OR "miq" OR "fis" OR "family impact scale" OR "qolip 10" OR "quality of life with implant prostheses qolip 10"))

AND

(TITLE-ABS-KEY (instrumentation OR "Validation Studies" OR "reproducibility of results" OR reproducib* OR "psychometrics" OR psychometr* OR clinimetr* OR clinometr* OR "observer variation" OR "discriminant analysis" OR reliab* OR valid* OR coefficient OR "internal consistency" OR (cronbach* AND (alpha OR alphas)) OR "item correlation" OR "item correlations" OR "item selection" OR "item selections" OR "item reduction" OR "item reductions" OR agreement OR precision OR imprecision OR "precise values" OR test-retest OR (test AND retest) OR (reliab* AND (test OR retest)) OR stability OR interrater OR inter-rater OR intrarater OR intra-rater OR intertester OR intertester OR intratester OR intra-tester OR interobserver OR inter-observer OR intraobserver OR intra-observer OR intertechnician OR inter-technician OR intratechnician OR intra-technician OR interexaminer OR inter-examiner OR intraexaminer OR intra-examiner OR interassay OR inter-assay OR intraassay OR intra-assay OR interindividual OR inter-individual OR intraindividual OR intra-individual OR interparticipant OR inter-participant OR intraparticipant OR intra-participant OR kappa OR kappa's OR kappas OR "coefficient of variation" OR repeatab* OR ((replicab* OR repeated) AND (measure OR measures OR findings OR result OR results OR test OR tests)) OR generaliza* OR generalisa* OR concordance OR (intraclass AND correlation*) OR

discriminative OR "known group" OR "factor analysis" OR "factor analyses" OR "factor structure" OR "factor structures" OR dimensionality OR subscale* OR "multitrait scaling analysis" OR "multitrait scaling analyses" OR "item discriminant" OR "interscale correlation" OR "interscale correlations" OR ((error OR errors)) AND (measure* OR correlat*or AND evaluat*or AND accuracy OR accurate OR precision OR mean) OR "individual variability" OR "interval variability" OR "rate variability" OR "variability analysis") OR (uncertainty AND (measurement OR measuring)) OR "standard error of measurement" OR sensitiv* OR responsive* OR (limit AND detection) OR "minimal detectable concentration" OR interpretab* OR ((small* AND (real OR detectable) AND (change OR difference)) OR "meaningful change" OR "minimal important change" OR "minimal important difference" OR "minimally important change" OR "minimally important difference" OR "minimal detectable change" OR "minimal detectable difference" OR "minimally detectable change" OR "minimally detectable difference" OR "minimal real change" OR "minimal real difference" OR "minimally real change" OR "minimally real difference" OR "ceiling effect" OR "floor effect" OR "Item response model" OR irt OR rasch OR "Differential item functioning" OR dif OR "computer adaptive testing" OR "item bank" OR "cross-cultural equivalence")))