ORIGINAL RESEARCH Public health

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Declaration of Interests: The authors certify that they have no commercial or associative interest that represents a conflict of interest in connection with the manuscript.

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https://doi.org/10.1590/1807-3107bor-2023.vol37.0022

Submitted: June 26, 2021 Accepted for publication: April 4, 2022 Last revision: April 20, 2022



Abstract: This study evaluated the construct validity of the instrument Oral Health Literacy among diabetics. A probabilistic random sample of 239 diabetics from an infinite population answered the 10 items of the questionnaire. The structural validity was assessed by confirmatory factor analysis and goodness of fit, chi-square per degrees of freedom ratio (X2/df), comparative fit index (CFI), goodness-of-fit index (GFI), and root-mean-square error of approximation (RMSEA). Internal consistency was estimated by the average variance extracted (AVE) and composite reliability (CR). The scores were dichotomized with the upper limit of the 95% confidence interval as the cutoff point. The three-dimensional model presented good quality parameters $(X^2/df = 2.459; CFI = 0.988; TLI = 0.981)$ and poor RMSEA (0.078). Internal consistency was adequate; AVE for the Access, Understand/appraise, and Apply subscales were 0.831, 0.981, and 0.954 and the CR for these subscales were 0.893, 0.962, and 0.822, respectively. Inadequate literacy ranged from 41.8 to 48.1%. The three-dimensional model identified (access, understand/appraise, and apply) showed structural validity, good internal consistency, and understandability.

Keywords: Psychometrics; Reproducibility of Results; Oral Health; Health Education, Dental; Diabetes Mellitus; Health Literacy.

Introduction

Health literacy involves personal, cognitive, and social skills to access, understand, evaluate, and apply information for health promotion, disease prevention, and maintenance of good health conditions, according to the theoretical model presented by Sørensen and collaborators in 2012.¹⁻³ Despite a focus on individual skills for making appropriate health decisions, a shift from the individual to a social focus is needed for better results, considering the interaction between individual skills and the demands of the health system. Health literacy aims to identify health inequality present in various population groups and^{4,5} it enables people to have greater control over the individual and social aspects of health and over the environmental determinants of health. The purpose of health literacy is to form and orient peoples' values, transforming knowledge and understanding about healthcare. Therefore, expanding access to information and improving the understanding of health-related issues



is crucial for improving personal and community health outcomes.^{1,4} The process involves self-efficacy, personal empowerment, civic engagement, and social interactions.⁴

The World Health Organization (WHO) has proposed an evidence-based global strategy for diet, physical activity, and health information.⁷ The approval and implementation of this strategy creates opportunities for health promotion and prevention of chronic non-communicable diseases8, resulting in lower costs for society.9 Low levels of health literacy are associated with complications of many diseases, including diabetes. Health policies should address the social determinants of health¹⁰ and promote interventions that target the causes of disease and the mechanisms by which social contexts affect health. These mechanisms can be modified by specific actions aimed at minimizing health inequities. Among the modifiable social determinants, access to preventive health measures¹¹ stands out, especially those aimed at preventing complications of chronic diseases, which include increasing health literacy.

Diabetes is a complex and multifactorial chronic disease, currently considered a global epidemic. It is estimated that Brazil in the year 2025 will rank 6th among countries with the highest number of diabetes cases, with 10.7 affected people per million.12 As a disease that develops throughout people's lives, diabetes and related complications have some preventable factors. The factors associated with type 2 diabetes (the most prevalent type) are potentially modifiable, including financial and non-financial factors at the individual level (access to care and information) and at the healthcare system level (patient tracking and treatment guideline adherence). A healthy lifestyle and access to information based on scientific evidence are important to reduce the preventable burden of diabetes and minimize complications.¹³ As the level of health literacy is correlated with diabetes knowledge and its prevention and treatment measures, it is important to effectively assess the level of health literacy of the community, and explore which interventions can promote health.14 Low levels of health literacy can make it difficult for healthcare professionals to communicate with their patients.¹⁵

People living with diabetes are more susceptible to oral diseases, including periodontal disease, which has a bi-directional relationship with diabetes.16 Efforts to increase primary prevention, improve the quality of care, reduce costs, and reduce inequalities in oral health could benefit from improvements in oral health literacy. Actions for oral health literacy must be offered in several contexts, especially in health services by health professionals and public policy makers. 17 Low levels of oral health literacy are linked to worse general and oral health outcomes,18 and educational actions and the consequent empowerment of patients with diabetes may contribute to the prevention of oral diseases. The collaboration of medical and dental professionals becomes more important in the treatment of individuals affected by diabetes mellitus as it increases patients' understanding and awareness of the relationship between diabetes mellitus and oral health.16

To evaluate the oral health literacy among people living with diabetes (OHLD) a questionnaire/scale was developed.¹⁹ The tool is applied in an interview, and it has 10 questions that are answered on a Likert-type scale. The quality of this instrument was previously assessed using content validity and reliability (internal consistency and reproducibility) parameters.¹⁹ The OHLD questionnaire was developed to measure the ability to access, understand, assess, and apply oral self-care to minimize complications and compensate for insulin resistance. However, the dimensional structure of the instrument must be evaluated to verify its construct validity and improve its understanding in different settings and populations. Several studies and systematic reviews have evaluated health literacy or related interventions among people with diabetes,^{20,21} but investigations on oral health literacy are scarce^{22,23} and no study was found on the quality and psychometric properties of an oral health literacy instrument for people with diabetes²⁴ considering its dimensional structure. The hypothesis of this investigation was that the OHLD has good quality, a four-dimension structure, a possible one-dimension structure, with

adequate validity and reliability to evaluate the construct "oral health literacy among people living with diabetes".

According to the theoretical model proposed by Sørensen et al.,¹ evaluations on health literacy must consider four conceptual dimensions: access, understanding, evaluation, and application of health-related information. Thus, the purpose of this study was to evaluate the quality of the OHLD and investigate its dimensional structure, internal consistency, and understandability, based on the Sørensen model.

Methodology

Ethical aspects

The study was conducted according to the ethical principles of Resolution 466/2012 of the National Health Council and the Declaration of Helsinki. The protocol was approved by and registered in the National Research Ethics Commission (CONEP) (protocol: 34687414.0.0000.5146).

Sampling procedure

The target population was people diagnosed with diabetes and under treatment in the public health service of a medium-size municipality (400,000 inhabitants). Participants were randomly selected from two primary health care units among the 73 units in the region. The selected units provide care to users from seven Family Health Strategy groups, the primary healthcare provider system adopted by the Brazilian Unified Health System.²⁵ For sample size calculation, the following parameters were used: 6.5% error, 5% non-response rate, and 95% confidence level (Z = 1.96). To perform a confirmatory factor analysis, a minimum of 20 cases per variable is needed.²⁶ For the proposed design, a sample of at least 24 cases for each item was sufficient to assess the quality of the OHLD instrument. After assessment of content validity by the expert committee, the OHLD was considered valid. Test-retest reliability and reproducibility were estimated using the simple kappa coefficient. The results were found to range from -0.09 to 1.19

The following inclusion criteria were considered: having a diagnosis of diabetes, being 18 years old

or older, and being registered in the Family Health Strategy system. All users of the two randomly selected health units were invited to participate, and those who accepted were interviewed by trained researchers. The exclusion criteria were: Portuguese was not the participant's native language, severe visual/hearing impairment (reported or perceived), drug or alcohol intoxication at the time of the interview, and age 60 years or over with cognitive impairment assessed by the Mini-Mental State Examination (MMSE).²⁸⁻³⁰ The sample loss was due to the participant's financial reasons for transportation and absence from home. Three to five attempts were made to contact the participant at home. Data collection was performed in the laboratory before or after the laboratory tests.

Diabetes diagnosis

The diagnosis of diabetes was confirmed by the medications used or by laboratory tests as proposed by the American Diabetes Association: fasting plasma glucose \geq 126 mg/dL; 2-h plasma glucose \geq 200 mg/dL; glycated hemoglobin \geq 6.5%; and in patients with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose \geq 200 mg/dL.³⁰

Oral Health Literacy among people living with Diabetes (OHLD) scale

Three items of the questionnaire explore the access to information including: the information provider (doctor, dentist, nurse, community health agent, family or others), the issues of the information (dental caries, root canal treatment, gingival problems / gingival bleeding, bone loss / tooth mobility, plaque index, dental trauma, bruxism / clenching, oral cancer, dental prosthesis, implant dental, orthodontic treatment, and others), and the source of the information (telephone, television, internet, radio, billboard, heard or viewed from others, newspaper, magazine, pamphlet / booklet, medication leaflet, medical prescription, mouthwash, toothpaste label and other texts). The access to information was estimated by five questions about the health professionals or people who passed on information about oral health. Twelve questions were about addressed issues and seventeen questions were about the sources of information, all with dichotomous (yes/no) answers. The responses of each category were summed and scores were calculated considering quintile approximate values in the case of merge values. The other seven items evaluated the understanding, appraisal, and application of the information and included questions about the level of importance of the information, if the quality and accuracy of the information was verifiable, if the advantages and disadvantages of different oral health treatments could be identified, and if the respondent incorporated the information on daily life, making appropriate choices based on the information received.

Statistical analysis

A descriptive analysis of the 10 items of the OHLD was performed to estimate the absolute and relative frequency (n, %), and the mean and standard deviation of the quantitative variables. The factorial structure of the OHLD was assessed with confirmatory factor analysis (AFC). Factor loading $(\lambda \ge 0.50)$ was used to assess factor variability and the chi-square to degrees of freedom ratio (X^2/df) was used to assess the goodness-of-fit of the model, with values less than 5 indicating an adequate model. The quality of the factorial model was assessed using the following parameters: the Bentler's comparative fit index (CFI), considered adequate if > 0.90, Tucker Lewis index (TLI), considered adequate if > 0.90, and root-mean-square error of approximation (RMSEA), considered adequate if < 0.05. The models (according to statistical indication) were estimated. Since the dimensions of the factorial model can generate a single construct, a reflective model of analysis was proposed. The software Statistical Package for Social Sciences (SPSS) version 24.0 (IBM) was used in the descriptive analysis and the SPSS Analysis of Moment Structures (AMOS) module was used for CFA. Internal consistency was estimated by Cronbach's alpha and composite reliability (CR). The average variance extracted (AVE) with values ≥ 0.5 and CR ≥ 0.7 indicated adequate convergent validity.^{26,31} The discriminant validity was assessed by comparing the AVE with the shared variance: the variance shared between the constructs cannot be greater than their respective extracted variances.

The three scale dimensions (Access, Understand/ Appraise, and Apply) were estimated using the weighted sum method, based on the estimates of the scores generated in the CFA. Next, exploratory analyses of the scores were conducted, estimating the minimum and maximum values, the average distribution, standard deviation and 95% confidence intervals (95%CI) of the generated scores. The scores can be interpreted in a quantitative or categorical way by dichotomization using the upper limit of the 95%CI as the cutoff point and creating the categories "adequate" and "inadequate". Then, the absolute values and percentages of the categories were estimated.

Results

A total of 239 people participated in the study (response rate: 95.6%). The mean age was 61.42 years (SD 12.85), ranging from 22 to 92 years, and 95%CI of 59.86 to 62.98. Mean formal education was 7.98 years (SD: 4.6, 95%CI: 7.39–8.57), ranging from 0 to 28 years. The majority (72%) received information related to oral health. Confirmatory factor analysis was performed after removing the data of people who reported not having access to information related to oral health in items 4, 5, 6, 7, 8, 9, and 10. Correlations between errors disappeared. The descriptive analysis of the OHLD scale are shown in Table 1.

The three-dimensional models presented good X²/df, CFI, TLI, RMSEA, AVE, CR, and Cronbach's alpha (Table 2). Three dimensions (access, understand/appraise and apply) were identified and the instrument showed proper structural validity, good internal consistency, and understandability. The three-dimensional model presented higher quality based on X²/df, CFI and TLI values and was considered the best model.

The OHLD overall and subscales scores (access, appraisal, understanding and application) with their minimum and maximum values, means, standard deviation, and 95%CI are shown in Table 3. In addition, the absolute and relative frequencies of inadequate literacy are presented.

Table 1. Description of the responses to each item of the instrument among individuals with diabetes.

Variable	n	%
OHLD		
Q1 Number of professionals/people who provided information on Oral Health		
O Never received information of professionals/people	81	33.9
1	107	44.8
2	34	14.2
3	6	2.5
4	11	4.6
Q2 Number of issues covered in the information on Oral Health		
Never received information of issues	70	29.
1 to 2	25	10.
3 to 5	49	20.
6 to 9	59	24.
10 to 12	36	15.
Q3 Number of media from which information on oral health was obtained		
Never received information of source	91	38.
1	37	15.
2	25	10.
3 to 6	47	19.
7 to 16	39	16.
Q4 Did you understand the oral health information that was presented		
Never received information of professionals/people, issues or source	67	28.
Did not understand / Understood very little	13	5.4
Understood partially	28	11.
Understood almost everything	37	15.
Understood everything	94	39.
Q5 Can you classify the information you have received about oral health into more or less important?		
Never received information of professionals/people, issues or source	67	28.
Cannot / Yes, but is very difficult	20	8.4
Yes, with difficulty	19	7.9
Yes, with little difficulty	22	9.2
Yes, easily	111	46.
Q6 Can you identify whether the information you have received about oral health is of good quality?		
Never received information of professionals/people, issues or source	67	28.
Cannot / Yes, but is very difficult	21	8.8
Yes, with difficulty	19	7.9
Yes, with little difficulty	13	5.4
Yes, easily	119	49.
Q7 Can you assess whether the information you have received about oral health is true or false?		
Never received information of professionals/people, issues or source	67	28.
Cannot / Yes, but is very difficult	20	8.4

Continue

ntinuation		
Yes, with difficulty	15	6.3
Yes, with little difficulty	16	6.7
Yes, easily	121	50.
Q8 Can you evaluate the advantages and disadvantages of different oral treatments, co	onsidering the information you have receive	ed\$
Never received information of professionals/people, issues or source	67	28
Cannot / Yes, but is very difficult	24	10
Yes, with difficulty	20	8.
Yes, with little difficulty	26	10
Yes, easily	102	42
9 Do you put into practice the information you received about oral health in your dail	y life?	
Never received information of professionals/people, issues or source	67	28
Never / Rarely	12	5.
Sometimes	43	18
Often	30	12
Always	87	36
Q10 Do you maintain a healthy behavior, considering the information you received abo	out Oral Health?	
Never received information of professionals/people, issues or source	67	28
Never / Rarely	10	4.
Sometimes	40	16
Often	33	13
Always	89	37

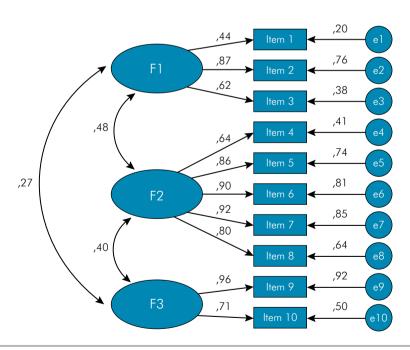


Figure. First-order three-dimensional model of the Oral Health Literacy of people with Diabetes questionnaire.

Table 2. Analysis of goodness-of-fit of the dimensional structures of Oral Health Literacy among people with Diabetes questionnaire.

Model	X²/df	CFI	TLI	RMSEA	AVE	CR	AC
Tri-dimensional – 1 st Order	1.586	0.979	0.970	0.058			
Factor 1 - Access					0,55	0.693	0.723
Factor 2 - Understand/Appraise					0,8	0.916	0.983
Factor 3 - Apply					0,81	0.828	0.968

X²/df: chi-square for degree of freedom ratio; CFI: Comparative Fit Index; TLI: Tucker Lewis Index; RMSEA: Root-Mean-Square Error of Approximation; AVE: Average Variance Extracted; CR: Composite Reliability; Alfa de Cronbach

Table 3. Overall scores of the Oral Health Literacy among people with Diabetes questionnaire for the 2nd order three-dimensional model and dimension (access, appraise / understand, and apply) scores in the 1st order three-dimensional model, with minimum and maximum values, means, standard deviation, 95%CI, and understandability.

Score	Minimum Maxi	h 4	aximum Mean	CD.	95%CI	Interpretation	Poor literacy	
		Maximum		SD		95%CI cut-off	n	%
Access	0.00	1.65	0.62	0.50	0.56-0.69	0.69	107	45.0
Understand/appraise	0.00	2.87	1.73	1.20	1.58-1.88	1.88	138	57.7
Apply	0.00	4.89	2.89	1.98	2.63-3.14	3.14	121	50.6

Discussion

The evaluation of the psychometric properties and the quality of instruments for the assessment of health-related outcomes, such as the OHLD, is important to ensure the adequate measure of the construct.²⁴ Validation studies are often incomplete, lacking, for example, CFA, which is necessary to establish construct validity. This study evaluated different dimensional structures of the OHLD and verified the quality of the different models that best represent the construct through the factorial validity and internal consistency. In addition, the different possibilities for score interpretation of the construct and its dimensions were presented.

The values of the standardized factorial loads of the items in the three-dimensional model were adequate. ¹⁹ The model presented a good fit and should be applied to measure the construct "Literacy in Oral Health among People Living with Diabetes". Acceptable values of internal consistency were obtained for the tested model, and, therefore, this methodological proposal ²⁶ is suitable to measure the theoretical concept with the best quality.

The "apply" dimension of the scale had a low influence of item 1 (number of professionals / people

who provided information on oral health). This may be explained by the prevalence of people who never received oral health information or received it from a single person or from a maximum of four people, which may limit the quality and amount of information received and, consequently, adapt health behaviors. Previous research has shown that communication between dentists and patients plays an important role in self-perception of treatment need and use of dental services, 32,33 consequently increasing the chance of adopting healthy behaviors and having better health conditions.

Low oral health literacy in people living with diabetes can contribute to the worsening of the disease. Diabetes can affect oral health, and it is the dentist's responsibility to monitor diabetic patients and alert them about this association³⁵. Poorly controlled diabetes can affect oral tissues in a similar way to what happens in other systems of the body.³⁵ Additionally, it is biologically plausible that chronic unresolved inflammation in the oral cavity has an impact on diabetes control. Significant independent associations between periodontal inflammation, glycemic condition, and complications of diabetes have been found.³⁶

An instrument that assesses oral health literacy in people with diabetes was not found in the literature.

The OHLD, using hierarchical measures, can be used in this specific population where the improvement of oral health can reflect in an improvement in the systemic condition.³⁶ The evaluation of the OHLD psychometric properties, quality, and understandability allows the future use of this instrument and guarantees reliable and valid conclusions, including the high internal consistency of the scale evaluated by Cronbach's alpha.²⁴

The overall OHLD scores and the scores of the access, appraisal, understanding, and application dimensions can be interpreted using statistical parameters (minimum and maximum values, means, standard deviation and 95%CI). However, the dichotomized score is also adequate and may be used to identify the profile of people living with diabetes whose levels of oral health literacy need to be assessed.

With an inclusive and integrative proposal, health literacy is one of the most promising approaches for improving public health outcomes, and essential to meet the challenging health demands of modern society.37 Health literacy involves the knowledge, motivation, and competence of people to access, understand, evaluate, and apply health information in order to make informed judgments and allow good decision-making in self-care and in the community, social, cultural, economic and political spheres. Possible factors dynamically associated with health literacy were presented in the model proposed by Sørensen e al.1 in 2012. Some of the factors are unchallengeable but others can be modified by health policies such as promotion of health service use, health costs management, promotion of healthy behaviors, improvement of health outcomes, people's participation and empowerment in health care, equity and maintenance of health education actions in health services, disease prevention, and health promotion.¹ Within this context, the validation of the OHLD allows its use in the clinical and research settings aimed at improving health conditions. As education and communication are fundamental to health literacy, the use of the OHLD contributes to the identification of modifiable variables with bidirectional effects on health literacy. These effects can be complex and should be the target of future research on disease prevention and health promotion strategies.¹

As a limitation, our results could not be compared with those of other studies, since our methodological approach and statistical analysis have been rarely used in the field of dentistry.38 Inter and intra-interviewer agreements were not estimated. The use of the maximum likelihood method, implemented by the AMOS software, can be considered another limitation, since it requires continuous variables and univariate and multivariate data normality. However, even in severe cases of data normality violation, the maximum likelihood method produces centered estimates, that is, estimates that tend towards the true population value, although their statistical significance tends to be inflated.³² On the other hand, for this analysis approach, when data violate the assumption of multivariate normality, a generally accepted rule is having 10 to 20 respondents per item,31 which was considered in the OHLD analysis.

Conclusion

The OHLD can be used considering the three-dimensional structure, which demonstrated factorial validity, internal consistency, reliability, and understandability. The overall score and dimension scores, considering the loading of each item, can be used as needed. It is hoped that the instrument can serve as a basis for future studies that aim to investigate this construct in different populations.

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