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DEVELOPMENT AND VALIDATION OF AN INSTRUMENT FOR THE EVALUATION OF HEALTH LITERACY REGARDING PERIODONTAL CONDITION AMONG PEOPLE WITH DIABETES

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ABSTRACT

The objective was to describe the process of developing and validating an instrument to assess the quality of Health Literacy regarding Periodontal Condition among people with Diabetes (LPCD).It is a methodological study conducted in a sample for construct validation of 129 people with diabetes (16 people per item) who answered eight questions, through an interview.**T**he content validity had the participation of 10 judges and the reliability was estimated by the Kappa test. Structural validity, on the other hand, was estimated via Confirmatory Factor Analysis (CFA). Internal consistency was assessed using *Cronbach's alpha* (CA) and *Composite Reliability* (CR). *Average Variance Extracted* (AVE) estimated convergent validity. Interpretability was measured by using the binary version of the LPCD considering the upper limit of the 95% confidence interval as the cutoff point. A three-dimensional model was generated which presented adjustment indexes considered adequate. In the assessment of internal consistency, it was found CA=0.979/0.986/0.949, considering the dimensions of access, understanding/evaluation and application, respectively. It was also observed the CR=0.978/0.981/0.947 as adequate values for access, understanding/evaluation and application, respectively. As for convergent validity, we identified AVE=0.977/0.960/0.948. In the dimensions of access, understanding/evaluation and application of the three-dimensional model, it was observed in a respective way 46.5%/45.0%/45.0% of inadequacy. LPCD presented structural validity, reliability and interpretability in the observed samples. The adjustment indexes were considered adequate, being able to choose its three-dimensional model.

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INTRODUCTION

The growing burden of chronic non-communicable diseases is the leading cause of morbidity and mortality worldwide (Wang, Naghavi e Allen, 2016) and therefore it is a threat to global health. Among these diseases, diabetes, a chronic disease caused by genetic and environmental factors, is clinically manifested as hyperglycemia (IDF, 2019; ADA, 2021). It is suggested that diabetes will affect more than 460 million people worldwide and by 2030, 7.8% of the world's adult population should live with it (IDF, 2019). Although its diagnosis, treatment and prevention have advanced significantly (Nathan DM, 2015), this disease is still among the top ten causes of death in the world and its prevalence is expected to increase (IDF, 2019). In addition, it is related to low quality of life (Jing *et al*., 2018), high need for medical care (Jiang *et al*., 2003), systemic complications and association with other chronic diseases, such as cardiovascular diseases (Matheus *et al.,* 2013). Type 2 diabetes accounts for 90% of cases, and can be preventable, as its main risk factors can be controlled through changes in people's lifestyles (Chatterjee*et al*., 2018, IDF, 2019). Therefore, it is important that people living with diabetes have access to information about this disease and how it can negatively affect their overall health with a view to adopting a healthy lifestyle. People with diabetes are more susceptible to oral diseases, including periodontal diseases, with a feedback relationship between diabetes and periodontal diseases (Lalla and Papapanou, 2011). Diabetes can affect the oralmicrobiome leading to a dysbiotic profile (Preshaw*et al.,* 2012; Corbella *et al,* 2013; Ismail *et al,* 2015; Xiao *et al*, 2017 and Teles*et al*, 2020), with increased level of cytokines due to inflammatory load in periodontal tissues and reduced bone homeostasis (Santos *et al* 2010 and Polak *et al*, 2020). People with type 2 diabetes are at increased risk of destructive periodontitis. In addition, the severity of periodontitis in

these people is directly related to poor glycemic control and complications, such as cardiovascular problems. It is suggested that periodontitis can lead to moderate hyperglycemia even in healthy individuals, making it a risk factor for diabetes (Grazian*iet al*, 2018 and Genco*et al,* 2020). There is a bidirectional relationship between diabetes and periodontal disease. The progression rate of periodontitis, according to the classification published in 2018, included the presence of diabetes and the level of glycated hemoglobin A1c (HbA1c) as parameters to be considered in periodontal treatment (normoglycemic HbA1c <7.0% and people with diabetes HbA1c ≥7.0%) with potential impact on systemic health (Papapanou *et al*., 2018). Therefore, it is extremely important that people living with diabetes and/or periodontal disease have an adequate level of knowledge about this two-way relationship to minimize complications and the burden of the disease. Despite this, such knowledge seems to be limited (Poudel *et al*, 2018). So, it becomes necessary and fundamental to reinforce the idea of health education, which forms the basis for the management and mastery of prevention strategies in order to intervene with less aggressive therapies and with a better prognosis for chronic non-communicable diseases. Health literacy (HL) comprises personal, cognitive and social skills that determine people's ability to access, understand, evaluate and apply the necessary information in health promotion, disease prevention and maintenance of good health conditions, according to the theoretical model presented by Sørensen and colleagues in 2012. Low levels of HL can promote complications of many diseases, including complications related to diabetes. Thus, there is a need to promote health policies that address the social determinants of health (WHO, 2007) that express the purpose of interventions on the causes of diseases and on the mechanisms by which social contexts affect health. The Family Health Strategy (FHS) is configured as a reference proposal that emerged in the 1990s, in Brazil, to encourage changes in the health care model in order to meet the requirements of the 1988 constitution and the principles of Brazil's National Health System (SUS) (Paim *et al*, 2011). In this sense, users need to have knowledge and access to this form of service. In addition, educational actions with increased literacy in oral health and empowerment of patients should be extended, contributing to disease prevention. Previous studies have evaluated health literacy, as well as interventions to improve literacy levels, among people with diabetes (Jacobs *et al.,* 2016 and Caruso *et al.*, 2017). Thus, oral health literacy is a relevant topic (Junkes *et al*., 2015 and Bado*et al,* 2018) and little investigated with regard to the evaluation of health literacy in relation to the periodontal condition of people with diabetes.

Questionnaires are assessment instruments that produce important data for research and their development and use must be surrounded by a lot of care. These concerns should be even greater in relation to research that seeks to assess the health condition of a specific population, as is the case of people with diabetes. In addition, no studies were found to assess the quality and psychometric properties of an instrument for assessing Health Literacy regarding Periodontal Condition among people with Diabetes (LPCD). An evaluation instrument was then developed covering the domains of HL with regard to the periodontal condition among people with diabetes. The quality of the LPCD instrument was investigated, considering the four dimensions of this construct: accessing, understanding, evaluating and applying information related to oral health. The construct's validity was assessed by means of Confirmatory Factor Analysis (CFA), based on the fitting quality of the estimated model, on the internal consistency, reliability and interpretability of the instrument (Mokkink*et al.,* 2010). It is an important instrument, since a specific one was not observed in the literature to assess the knowledge and type of information received about the periodontal condition among people with diabetes, with regard to HL.

MATERIALS AND METHODS

Methodological study that focused on the development, verification of reliability, validation and interpretability of the instrument on oral health literacy regarding periodontal condition among people with diabetes (LPCD). This study was developed in two stages: the first was centered on the definition of the theoretical question referring to the theme "oral health literacy regarding the periodontal condition among people with diabetes"; followed by a literature review aiming at scientific basis in the process of development of the LPCD. A questionnaire composed of 61 items was developed, divided into 17 questions related to access, understanding, evaluation and application of information received about periodontal condition among people with diabetes, considering the conceptual theoretical model of Sørensenand colleagues (2012). The development of these questions was carried out by two researchers (MBM and AMEBLM). This first version was sent to a committee of experts, for content validation and later face validation. The instrument was evaluated by 10 judges who should also designate, in writing, suggestions so that the items could be improved. As a final result, the instrument was left with 08 questions that contemplate the dimensions: access, understanding, evaluation and application, with answers on a Likert-type scale. Three physical health units that serve one, three and four health teams from the Family Health Strategy (FHS) were randomly selected from among the 73 physical health units existing at the time of the study. The inclusion criteria were: having a diagnosis of diabetes confirmed through the verification of the use of medication or laboratory tests as proposed by the *American Diabetes Association*: fasting plasma glucose ≥126 mg/dL; 2 hours of plasma glucose ≥ 200 mg/dL; glycated hemoglobin ≥ 6.5%; in patients with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥ 200 mg/dL[2]; being 18 years old or over and registered in the FHS record.

The selected ones were invited to participate. Those who accepted were interviewed. The LPCD was applied and reapplied to 60 people assisted in the physical unit that had an FHS team. Its reliability was estimated using the Kappa index to measure the level of agreement. The Kappa index is an adjusted agreement indicator that ranges from "minus 1" to "plus 1" - the closer to 1 the better the level of agreement; its distribution and the respective levels of interpretation are: <0.00 = bad; 0.00 to 0.20 = weak; 0.21 to 0.40 = poor; 0.41 to 0.60 = regular; 0.61 to 0.80 = good; 0.81 to 0.99 = excellent; 1.00 = perfect (Landis and Koch, 1977). The minimum value of 0.70 was adopted for satisfactory internal consistency. Internal consistency was assessed using Cronbach's α, which can vary from 0.00 to 1.00; the higher the coefficient, the more homogeneous the instrument is. When items are used to scale, they must have internal consistency. All items must measure the same thing, so they must be correlated with each other. Cronbach's alpha has a straightforward interpretation. To compare groups, values from 0.7 to 0.8 are considered satisfactory. For clinical application, much higher values between 0.90 and 0.95 are required (Bland and Altman, 1997). In the second stage of the research carried out in the two other physical units, which had 3 and 4 FHS teams respectively, where 129 people from a non-probabilistic sample idealized for carrying out confirmatory factor analysis were evaluated[31]. The questionnaires were applied through interviews. After clearing out the research objectives, those who agreed to participate signed an Informed Consent Form. As for the statistical analysis, initially a descriptive analysis was carried out in order to characterize the socioeconomic and demographic profile, through the estimates of absolute (n) and relative (%) frequencies; the mean and standard deviation of the quantitative variables. Subsequently, the population of 129 people with diabetes was characterized as to the 08 questions or items of the LPCD instrument. The Kappa coefficient was estimated and the internal consistency was assessed by Cronbach's alpha. For the analysis of the construct validity, a confirmatory factor analysis was used. As a quality indicator of local adjustment, we used the factorial weight ($\lambda \geq 0.50$). This technique allows the identification of the smallest possible number of factors (or dimensions/constructs) that best explain the correlations between the questions of the indicators. To assess the quality of the global fit of the model, the following parameters were used: ratio between the chi-square value and the number of degrees of freedom ($X^2/g.l$), wherevalues less than 5 indicate an adequate model. The quality of the factorial model was assessed using the following indices: *Comparative Fit Index (CFI)*; *Tucker-Lewis Index (TLI);Goodness-of-Fit Index (GFI),* considered adequate if > 0.90 and

Root-Mean-Square Error of Aproximation (RMSEA) considered adequate if < 0.05. The three-dimensional model of the LPCD was estimated, according to statistical indication. The convergent construct validity was estimated by *Averange Variance Extracted* (AVE) with appropriate values above or equal to 0.5, and by *Composite Reliability* (CR), considering adequate values greater than or equal to 0.7. Convergent validity was also assessed through the analysis of the factorial loads of the items in the questionnaire. Factor load values ≥ 0.50 were indicators of convergent validity (Hair *et al*., 2005). Discriminant validity was demonstrated by comparing the AVE of two factors with the square of the correlation coefficient between those factors, considering the discriminant validity when the factors' AVE were greater than or equal to the square of the correlation between them (Maroco 2010). The SPSS software, version 24.0, was used for descriptive statistical analysis and its AMOS module for factor analysis. The ethical principles of Resolution 196/96 of the National Health Council, in accordance with the Declaration of Helsinki, were respected. The research was approved and registered by the National Research Ethics Commission (CONEP) (protocol number: 34687414.0.0000.5146).

RESULTS

The first stage of the study included 60 people with a mean age of 60.04 years, a standard deviation of 13.42 and a confidence interval between 56.30 and 63.78. The average level of education was 8.37 years of study, with a standard deviation of 4.52 and a confidence interval between 7.11 and 9.63. The average per capita income was 863.64 reais, with a standard deviation of 782.05 and a confidence interval of 645.92 to 1081.37. In the statistical analysis of the data referring to the second stage, a total of 129 people answered the questionnaire. They were between 22 and 83 years old, with a mean age of 60.30 years with a standard deviation of 11.35 and a confidence interval of 58.24 to 62.36. They had an education level of 8.77 years of study, with a standard deviation of 4.45 years and a confidence interval between 7.96 to 9.58. The average per capita income reported was 811.61 with a standard deviation of 706.59 and a confidence interval ranging from 683.34 to 939.88. The descriptive measures of the respondents' socioeconomic and demographic conditions can be seen in Table 1.

Table 1. Socioeconomic and demographic conditions of respondents of the Oral Health Literacy instrument regarding Periodontal Condition among people with Diabetes, considering the participants in the first and second stage of research

Variable	n	%	N	%
Sex*				
Male	18	32.7	44	34.6
Female	37	67.3	83	65.4
Self-reported skin color or race*				
White	12	21.8	37	29.8
Yellow	3	5.5	8	6.5
Black	12	21.8	20	16.1
brown	28	50.9	58	46.8
Indigenous			1	0.8
Marital status*				
Single	5	9.4	20	16.4
Married	34	64.2	76	60.8
Common-law marriage	3	5.7	6	4.8
Widowed	3	5.7	14	11.2
Divorced/separated	8	15.1	9	7.2
Age*				
22-59	26	46.4	55	43.0
60-83	29	51.8	73	57.0
Education level*				
12 or more years	11	20.0	34	26.4
9-11	17	30.9	32	24.8
5-8	14	25.5	34	26.4
1-4	9	16.4	22	17.1
0	4	7.3	5	3.9
Per capita income*				
More than a minimum wage	15	28.8	27	22.5
Half to one minimum wage	15	28.8	45	37.5
Less than half a minimum wage	22	42.3	48	40.0

Still considering the initial phase, a total of 60 pairs of answers were considered in the analysis of reproducibility for the 17 questions analyzed. In this stage, nine questions were excluded, whose objective was only to characterize and not to assess literacy regarding the periodontal condition. As a result, the questionnaire was shorter and easier to apply and understand. Once this was done, the Kappa test was performed for each of the questions, with adequate values ranging from 0.71 to 0.97. These values are shown in Table 2, as well as the values referring to Cronbach's Alpha. Eight questions were considered for confirmatory factor analysis, and a first order three-dimensional model was generated, considering the dimensions of access, understanding/evaluation and application. In the figure, the values of the standardized factorial weights of the items in the measurement model were adjusted according to the latent dimensions and their correlations (Figure 1).

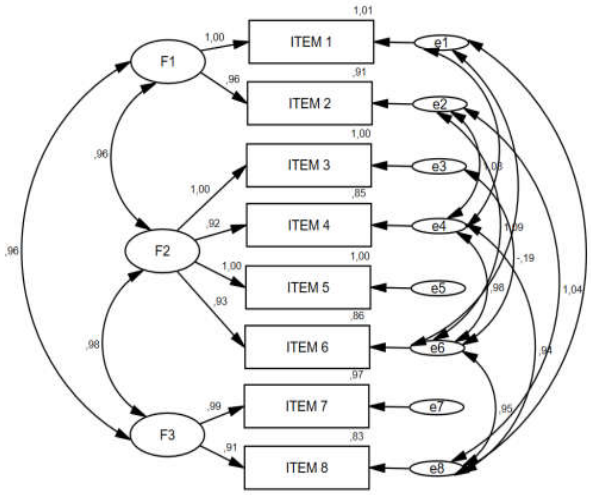

Figure 1. First order three-dimensional model of Literacy regarding Periodontal Condition among people with Diabetes, adjusted by confirmatory factor analysis

Among respondents, most received information related to oral health, ranging from 53.5 to 55%. Table 3 presents the questions that made up each dimension. The questionnaire validation process, therefore, allowed it to present, at the end, 08 questions distributed in three dimensions. In the analysis of the fit quality indicators of the models, it was observed that the three-dimensional model presented adequate values for $X^2/g.l$=1.571; *CFI*=0.999; TLI=0.995 e RMSEA=0.067. A 0.979 Cronbach's Alpha was found; 0.986 and 0.949, considering the dimension access, understanding/evaluation and application, respectively. Satisfactory values were estimated for the AVE (0.977, 0.960 and 8.948) and for the CR (0.978, 0.981 and 0.947) considering the three dimensions evaluated.Scores for the dimensions were presented: access, understanding/evaluation and application with their respective minimum values, maximum values, means, standard deviation and 95% CI. The interpretability of the scores considered the upper limit of the 95% CI as the cutoff point. In addition, the absolute and relative frequencies of inadequate literacy were presented (Table 4).

DISCUSSION

Questionnaires produce important data for research and their development and use must be surrounded by great care. These concerns should be even greater in relation to research that seeks to assess issues related to HL, as is the case of this instrument. The interview model was chosen and the questionnaire developed was completed with minimal intervention by the researcher. The validation of the instrument resulted in the exclusion of a large number of questions (n = 09) from the original scale, since these questions were responsible only for characterizing the instrument and were not able to measure the literacy itself. Even so, the remaining questions continue to address the dimensions defined by the conceptual model that was followed (Sørensen *et al*., 2012).

Table 2. Values referring to the Kappa index to measure the level of agreement and Cronbach's alpha to assess the internal consistency of the LPCD construct

Variable	Kappa	P value	Cronbach's alpha
LPCD			
Q1 Access / When was the last time you read information about your periodontal condition?	0.90	0.000	0.959
Q2 Understanding / Did you understand the information you read about the periodontal condition?	0.74	0.000	0.982
Q3 Evaluation / Can you assess the quality of the information you read about the periodontal condition?	0.71	0.000	0.982
Q4 Application / Do you put into practice the information you read about the periodontal condition?	0.84	0.000	0.949
Q5 Access / When was the last time you watched or heard information about the periodontal condition?	0.97	0.000	0.959
Q6 Understanding / Did you understand the information you watched or heard about the periodontal condition?	0.80	0.000	0.982
Q7 Evaluation / Can you assess the quality of the information that you watched or heard about the periodontal condition?	0.94	0.000	0.982
Q8 Application / Do you put into practice the information you watched or heard about the periodontal condition?	0.92	0.000	0.949

Table 3. Dimensions obtained after factor analysis and respective questions, validation of the questionnaire construct for the evaluation of the Literacy instrument regarding Periodontal Condition among people with Diabetes

Variable	N	%
LPCD		
Q1 Access / When was the last time you read information about your periodontal condition?		
Never read information	56	43.4
More than 2 years ago	3	2.3
In the last 2 years	1	.8
Last year	3	2.3
In the last 6 months	43	33.3
Last month	23	17.8
Total	129	100.0
Q2 Understanding / Did you understand the information you read about the periodontal condition?		
Never read	57	44.2
Understood partially	4	3.1
Understood almost everything	18	14.0
Understood everything	50	38.8
Total	129	100.0
Q3 Evaluation / Can you assess the quality of the information you read about the periodontal condition?		
Never received information	57	44.2
Yes, with difficulty	1	.8
Yes, with little difficulty	19	14.7
Yes, easily	52	40.3
Total	129	100.0
Q4 Application / Do you put into practice the information you read about the periodontal condition?		
Never read information	56	43.4
Rarely	2	1.6
Sometimes	10	7.8
Often	39	30.2
Always	22	17.1
Total	129	100.0
Q5 Access / When was the last time you watched or heard information about the periodontal condition?		
Never watched or heard information	56	43.4
More than 2 years ago	1	.8
In the last 2 years	1	.8
Last year	5	3.9
In the last 6 months	40	31.0
Last month	26	20.2
Total	129	100.0
Q6 Understanding / Did you understand the information you watched or heard about the periodontal condition?		
Never watched or heard	56	43.4
Understood partially	3	2.3
Understood almost everything	19	14.7
Understood everything	51	39.5
Total	129	100.0
Q7 Evaluation / Can you assess the quality of the information that you watched or heard about the periodontal condition?		
Never watched or heard information	56	43.4
Yes, with difficulty	1	.8
Yes, with little difficulty	19	14.7
Yes, easily	53	41.1
Total	129	100.0
Q8 Application / Do you put into practice the information you watched or heard about the periodontal condition?		
Never watched or heard information	56	43.4
Rarely	1	.8
Sometimes	6	4.7
Often	35	27.1
Always	31	24.0
Total	129	100.0

Table 4. General Literacy scores for Periodontal Condition among people with Diabetes: access, understanding / evaluation and application with their respective minimum values, maximum values, means, standard deviation, confidence intervals and interpretability

Score	Minimum value	Maximum value	Mean	Standard deviation	Confidence interval 95%	Interpretability Cutoff point HL of CI 95%	Inadequate	
							n	%
Access	-1.57	5.50	2.28	2.18	1.90-2.66	2.66	60	46.5
Understanding/Evaluation	-0.08	5.63	2.59	2.34	2.18-3.00	3.00	58	45.0
Aplication	0.00	4.80	2.31	2.08	1.94-2.67	2.67	58	45.0

Issues related to access, understanding/evaluation and application of information related to health literacy regarding periodontal condition among people with diabetes are satisfactorily addressed. These dimensions and respective questions have sufficient validity and reliability for their application in contexts that want to evaluate oral health literacy within the criteria for which the questionnaire was validated. All 08 questions have a factor load within the parameters previously established. Cronbach's alpha values were considered good. The choice for the three-dimensional model resulted from the statistical indication that indicated the most appropriate model. In relation to the proposed theoretical model, it is important to highlight that the questions in the final version of the questionnaire address all the attributes initially defined for assessing HL regarding the periodontal condition in the specific population evaluated.

Low levels of health literacy can promote complications of many diseases, including complications related to diabetes. Educational actions with the increase of literacy in oral health and the consequent empowerment of patients with diabetes contribute to the prevention of oral diseases.Therefore, the evaluation of the psychometric properties and the quality of instruments for evaluating events related to oral health, such as the LPCD, is important to ensure the appropriate measure of this construct (Mokkink*et al*., 2010). The CFA is necessary in the process of validating measuring instruments, as well as in confirming the dimensional structure originally proposed. In this sense, this study evaluated the most appropriate dimensional structure of the LPCD, as well as verified the quality of the model that best represents the construct through factorial and convergent validity. The values of the standardized factor weights of the items in the three-dimensional model were considered adequate. The results showed the possibility of using a three-dimensional structure for the LPCD. The model presented adequate adjustments for all evaluated parameters. Internal consistency and reliability were also considered satisfactory (Hair *et al*., 2005 and Maroco, 2010). The carried out analyzes showed that in the access dimension, most respondents reported having read, watched or heard information regarding their periodontal condition. This demonstrates the importance of the relationship between health professionals and the patient, allowing greater contact between them, a situation that can improve access and increase the application and maintenance of appropriate behavior in relation to oral health in the evaluated population. Previous research has shown that communication between dentists and their patients plays an important role in self-perceiving the need for treatment, using dental services (Martins *et al*, 2008 and Schönwetter *et al.,* 2012) and, consequently, an increased chance of adopting healthy behaviors and better health conditions. The person living with diabetes may present oral alterations, and the dentist must observe and alert them about the association between oral alterations and diabetes (Nelson, 2008).

A set of information about the consequences of poorly controlled diabetes suggests that oral tissues can be affected in a similar way to what happens in other systems of the body (Taylor *et al,* 1996). Chronic unresolved inflammation due to oral changes, with periodontitis has an impact on diabetes control. Associations were observed between periodontal inflammation, glycemic condition and diabetes complications (Chapple and Genco, 2013). As an instrument that assesses oral health literacy regarding periodontal condition among people with diabetes has not been found in the literature, it is believed that the creation of the LPCD may contribute to the theme. Models like these can be used in specific populations where the knowledge about periodontal condition can reflect in an improvement of the oral health as a whole, which also contributes in the improvement of the systemic condition (Chapple and Genco, 2013).The evaluation of the psychometric properties, quality and interpretability of the LPCD allows for greater security as to the quality of the instrument and its use in future investigations that consider it. The results referring to the construct and convergent validities enable valid, reliable and easy-to-interpret conclusions (Mokkink *et al*, 2010). Health literacy must consider the knowledge, motivation and competence of people to access, understand, evaluate and apply health information in order to make judgments and encourage decision-making in relation to self-care and also in the community, social, cultural, economic and political spheres (Sørensen *et al*., 2012). In this context, the statistical validation of the LPCD construct allows the inference of its adequacy as an instrument applicable to the clinical scenario and research aiming at improving health conditions, making people's education and communication between professionals and patients better. Oral health literacy is a relevant topic, but little investigated with regard to the evaluation of HL in relation to the periodontal condition of people with diabetes. In addition, no studies were found to be considered gold standard when evaluating this issue addressed in our study. Thus, the instrument's accuracy was not performed due to the lack of a standard for comparison. One limitation observed was the non-direct comparison of the results obtained with the literature, since it is a methodological approach not identified in previous studies, since the statistical analysis techniques adopted have been little used in the field of dentistry (Zucoloto *et al.,* 2014). LPCD can be used considering its three-dimensional structure in people living with diabetes. The evaluated models demonstrated the presence of factorial and convergent validity, showing the mselves as a valid, reliable and easily interpretable instrument to assess the proposed construct. We hope that the version of the instrument evaluated for its quality can serve as a basis for future studies that seek to investigate this construct in different populations. The interpretability of its general scores regarding the dimensions evaluated with their respective minimum values, maximum values, means, standard deviation and 95% CI is feasible. In this context, the statistical validation of the LPCD allows the inference of its adequacy as an instrument applicable to the clinical scenario and research aimed at improving health conditions. Good levels of literacy regarding oral health, especially with regard to periodontal condition among people with diabetes, are necessary because low levels of such literacy can contribute to the worsening of this disease. It was observed that although most people have access to information about the periodontal condition, most of the interviewees still do not receive, understand, evaluate or put this information into practice.

CONCLUSION

We conclude that the development and validation of this instrument enables an evaluation strategy that is easy to carry out for health literacy regarding the periodontal condition of people with diabetes, based on a theoretical framework that contemplates the integrality and essential dimensions for this type of population. The results obtained may sensitize managers to qualify health services and professional practices, in order to improve the population's access to adequate information and that allow the understanding / evaluation and application of this information received.

Appendix: Appendixes, if needed, appear before the acknowledgment.

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REFERENCES

American Diabetes Association (ADA). 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2021. Diabetes Care. 2021;44(1): S15-S33.

Bado, F. M. R., Rebustini, F., Jamieson, L., Cortellazzi, K. L., &Mialhe, F. L. (2018). Evaluation of the psychometric properties of the Brazilian version of the Oral Health Literacy Assessment in Spanish and development of a shortened form of the instrument. PloS one, 13(11), e0207989

Bland JM, Altman DG. Alfa de Cronbach. *BMJ* . 1997; 314 (7080): 572. doi: 10.1136 / bmj.314.7080.572.

Caruso R, MAgon A, Baroni I, Dellafiore F, Arrigoni C, Pitella F, Ausll D. Health literacy in type 2 diabetes patients: a systematic review of systematic reviews. Acta Diabetol. 2017; *55*(1), 1-12.

Chapple ILC, Genco R, working group 2 of the joint EFP/AAP workshop. Diabetes and periodontal diseases: consensus report of the Joint EFP/AAP Workshop on Periodontitis and Systemic Diseases. J Periodontol. 2013;84(4):S106-12.

Chatterjee S, Davies MJ, Heller S, Speight J, Snoek FJ, Khunti K. Diabetes structured self-management education programmes: a narrative review and current innovations. Lancet Diabetes Endocrinol 2018;6:130-142.

Corbella S, Francetti L, Taschieri S, Siena F, Del Fabbro M. Effect of periodontal treatment on glycemic control of patients with diabetes: A systematic review and meta-analysis. J Diabetes Investig 2013; 13;4:502-9.

Genco RJ, Graziani F, Hasturk H. Effects of periodontal disease on glycemic control, complications, and incidence of diabetes mellitus.Periodontol 2000 2020;83:59–65.

Graziani F, Gennai S, Solini A, Petrini M. A systematic review and meta-analysis of epidemiologic observational evidence on the effect of periodontitis on diabetes An update of the EFP-AAP review. J ClinPeriodontol2018;45:167–87.

Hair JF, Black WC, Babin B, Anderson RE, Tatham RL (2005). Multivariate data analysis, 6th ed. New York City, NY: Prentice Hall.

International Diabetes Federation. IDF Diabetes Atlas, 9thedn. Brussels: International Diabetes Federation, 2019.

Ismail AF, McGrath CP, Yiu CKY. Oral health of children with type 1 diabetes mellitus: A systematic review. Diabetes Res ClinPract 2015;108:369–81.

Jacobs RJ, Lou JQ, Ownby RL, Caballero J. A systematic review of eHealth interventions to improve health literacy.Health Informatics J. 2016;22(2):81-98.

Jiang HJ, Stryer D, Friedman B, Andrews R. Multiple Hospitalizations for Patients With Diabetes. Diabetes Care 2003; 26:1421-1426.

Jing X, Chen J, Dong Y, *et al*. Related factors of quality of life of type 2 diabetes patients: a systematic review and meta-analysis. Health Qual Life Outcomes 2018;16:189.

Junkes MC, Fraiz FC, Sardenberg F, Lee JY, Paiva SM, Ferreira FM. Validity and reliability of the Brazilian version of the Rapid Estimate of Adult Literacy in Dentistry: BREALD-30. *PLoS ONE,* 2015;10(7):e0131600.

Lalla E, Papapanou PN. Diabetes mellitus and periodontitis: a tale of two common interrelated diseases. Nat RevEndocrinol. 2011;7(12):738-48.

Landis JR, Koch GG. The measurement of observer agreement for categorical data.Biometrics. 1977 Mar;33(1):159-74. PMID: 843571.

Maroco J. Análise de Equações Estruturais: Fundamentos teóricos, software & aplicações. PêroPinheiro: EdiçãoemPortuguês. 2010.

Martins AMEBL, Barreto SM, Pordeus IA. Fatores relacionados à autopercepção da necessidade de tratamento odontológico entre idosos. Rev Saúde Pública 2008;42:487-96.

Matheus AS, Tannus LR, Cobas RA, Palma CC, Negrato CA, Gomes MB. Impact of diabetes on cardiovascular disease: an update. Int J Hypertens 2013; 2013:653789

Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, *et al*. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res. 2010;19(4):539-49.

Nathan DM. Diabetes: Advances in Diagnosis and treatment. JAMA 2015;314:1052-1062.

Nelson RG. Periodontal disease and diabetes. Oral Dis. 2008;14(3):204-5.

Paim J, Travassos C, Almeida C, Bahia L, Macinko J. The Brazilian health system: history, advances, and challenges. Lancet. 2011;377(9779):1778-97.

Papapanou PN, Sanz M, Buduneli N, Dietrich T, Feres M, Fine DH, *et al*. Periodontitis : Consensus report of workgroup 2 of the 2017 World Workshop on the Classification of Periodontal and Peri Implant Diseases and Conditions. J ClinPeriodontol 2018;45:162–70.

Polak D, Sanui T, Nishimura F, Shapira L. Diabetes as a risk factor for periodontal disease—plausible mechanisms. Periodontol 2000. 2020;83:46–58.

Poudel P, Griffiths R, Wong VW, Arora A, Flack JR, Khoo CL, *et al*. Oral health knowledge, attitudes and care practices of people with diabetes: A systematic review. BMC Public Health 2018;18:1–12.

Preshaw PM, Alba AL, Herrera D, Jepsen S, Konstantinidis A, Makrilakis K, *et al*. Periodontitis and diabetes: A two-way relationship. Diabetologia 2012;55:21–31.

Santos VR, Lima JA, Gonçalves TED, Bastos MF, Figueiredo LC, Shibli JA, *et al*. Receptor Activator of Nuclear Factor-Kappa B Ligand/Osteoprotegerin Ratio in Sites of Chronic Periodontitis of Subjects With Poorly and Well-Controlled Type 2 Diabetes. J Periodontol 2010;81:1455–65.

Schönwetter DJ, Wener ME, Mazurat N. Determining the validity and reliability of clinical communication assessment tools for dental patients and students. J Dent Educ. 2012;76(10):1276-90.

Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, *et al*. Health literacy and public health: a systematic review and integration of definitions and models. BMC Public Health. 2012;12:80.

Taylor GW, Burt BA, Becker MP, Genco RJ, Shlossman M, Knowler WC, *et al*. Severe periodontitis and risk for poor glycemic control in patients with non-insulin-dependent diabetes mellitus. J Periodontol. 1996;67(10):1085-93.

Teles F, Wang Y, Hajishengallis G, Hasturk H, Marchesan JT. Impact of systemic factors in shaping the periodontal microbiome.Periodontol 2000 2020;1–37.

Xiao E, Mattos M, Vieira GHA, Chen S, Corrêa JD, Wu Y, *et al*. Diabetes Enhances IL-17 Expression and Alters the Oral Microbiome to Increase Its Pathogenicity. Cell Host Microbe 2017;22:120-128.e4.

Wang H, Naghavi M, Allen C. Global, regional, and national life expectancy, all-cause mortality, and cause-specific mortality for 249 causes of death, 1980–2015: a systematic analysis for the Global Burden of Disease Study 2015. Lancet 2016; 388:1459–1544.

World Health Organization (WHO).A conceptual framework for action on the social determinants of health.Geneve: Commission on Social Determinants of Health.[Internet]. 2007 [cited 2021 Jan 06]; [about 1-77 p.]. Available from: https://www.who.int/social_determinants/resources/csdh_framework_action_05_07.pdf

Zucoloto ML, Maroco J, Campos JA.Psychometric Properties of the Oral Health Impact Profile and New Methodological Approach.J Dent Res. 2014;93(7):645-50.

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