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Article

Validation of the Oral Health Impact Profile in Spanish for Paraguayan adults (OHIP-14Py).

Validación del Perfil de Impacto de Salud Oral en español para adultos paraguayos (OHIP-14Py).

Clarisse Díaz-Reissner.[1]
Juan Roldán-Merino.[2,3,4,5]
Irma Casas García.[6,7,8]

Affiliations:
[1]Facultad de Odontología. Universidad Nacional de Asunción. Asunción, Paraguay.
[2]Sant Joan de Déu-Fundació Privada. Barcelona, Spain.
[3]Universitat Autònoma de Barcelona. Barcelona, Spain.
[4]Rovira i Virgili University of Tarragona. Tarragona, Spain.
[5]Research Group GEIMAC, Barcelona, Spain.
[6]Universitat Autònoma de Barcelona. Departamento de Pediatría, Obstetricia y Ginecología y Medicina Preventiva. Barcelona, Spain.
[7] Preventive Medicine Service. Hospital Germans Trias i Pujol. Barcelona, Spain.
[8]Research Group Innovation in Respiratory Infections and Tuberculosis Diagnosis (Group Consolidat 2017 SGR 494).

Corresponding author: Clarisse Díaz-Reissner. Facultad de Odontología de la Universidad Nacional de Asunción. Avda España c/ Brasil N° 430. Asunción, Paraguay. **E-mail:** cdiazr@odo.una.py

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Abstract: Objetive: The objective of this study was to culturally adapt and validate the short version of the Oral Health Impact Profile (OHIP) instrument into Spanish for use by Paraguayan adults who attended dental clinics. **Material and methods:** The design was a cross-sectional observational study based on Classical Test Theory (CTT). The original English language version was subjected to a forward-backward translation processes; a calibration of the examiners and pilot test were performed. The questionnaire was applied by dentists through interviews; the same dentists also made the oral examination. The dimensionality of the questionnaire was evaluated using Confirmatory Factorial Analysis (CFA). The total and item-total internal consistencies were evaluated using Cronbach's alpha. To evaluate the discriminating validity, the Mann-Whitney and Kruskal-Wallis tests were used. Spearman's correlation analysis was used to measure convergent validity for total-dimension, self-assessment of oral health, and dental caries experience index with the DMFT Index. **Results:** Three-hundred-thirty-three patients participated in the study. The CFA indicates the Paraguayan's OHIP (OHIP-14Py) is considered a multi-dimensional instrument. The Cronbach's alpha values were appropriate for both the total (α=0.061) and for item total (α=0.80) correlation. The OHIP-14Py discriminated for the variable self-perception of oral health (p=0.001), symptoms of the temporomandibular joint (TMJ) (p=0.026), need of upper dental prosthesis (p=0.001), need of lower dental prosthesis (p=0.001), and ≥20 teeth healthy (p=0.001). For measuring convergent validity, all coefficients of correlation were statistically significant (p=0.001). **Conclusion:** The OHIP-14Py is a reliable and valid questionnaire for the evaluation of oral health-related quality of life in Paraguayan adults.

Keywords: Quality of Life; Oral Health; Self Concept; Sickness Impact Profile; Validation Study; Paraguay.

Resumen: Objetivo: El objetivo del estudio fue adaptar culturalmente y validar el instrumento Perfil de Impacto de Salud Oral (OHIP) en la versión corta de 14 ítems en español, en adultos paraguayos que acudieron a consultorios odontológicos durante el primer trimestre del año 2017. **Material y Métodos:** El diseño del estudio fue transversal, basado en la Teoría Clásica de los Test (TCT). La versión original en inglés fue sometida al proceso de traducción-retraducción. Se realizó calibración de exa-minadores y prueba piloto. El cuestionario fue aplicado por odontólogos mediante entrevista, quienes además realizaron examen bucal.

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Se evaluó la dimensionalidad del cuestionario mediante el Análisis Factorial Confirmatorio (AFC). La consistencia interna fue evaluada mediante Alfa de Cronbach (α) para total e ítem-total. Se evaluó la validez discriminante utilizando las pruebas de Mann-Whitney y Kruskal-Wallis, validez convergente utilizando correlación de Spearman para total-dominio, autoevaluación del estado de salud oral e índice de experiencia de caries CPO-D. **Resultados:** Participaron del estudio 333 pacientes de 18 a 59 años. El AFC se consideró al instrumento multidimensional. Para el total α=0,861 y para correlación ítem-total al suprimir cada elemento α=0,80 siendo todos adecuados. Discriminó para las variables autoevaluación de salud bucal (p=0,001), síntomas de ATM (p=0,026), necesidad de prótesis superior (p=0,001) e inferior (p=0,001) y ≥20 dientes sanos (p=0,001). Todos los coeficientes de correlación de Spearman resultaron estadísticamente significativos con p=0,001. **Conclusión:** El OHIP-14Py es un cuestionario fiable y válido para la evaluación de la calidad de vida relacionada con la salud oral en adultos paraguayos.

Palabra Clave: *Calidad de Vida; Salud Bucal; Autopercepción; Perfil de Impacto de Enfermedad; Estudio de Validación; Paraguay.*

INTRODUCTION.

Two thirds of the world's population cannot access adequate oral health services, due to low coverage of primary health care, and there are inequalities between and within countries. In this setting, oral diseases can result in the loss of teeth, more-so in those of lower socio-economic strata, ethnic minorities, and immigrants, reducing oral health quality and quality of life,[1] which worsens as dental decay and periodontal attachment loss accumulate over a lifetime.[2]

For this reason, Federal Dental International (FDI) has defined oral health as: "multi-faceted and includes the ability to speak, smile, smell, taste, touch, chew, swallow and convey a range of emotions through facial expressions with confidence and without pain, discomfort and disease of the craniofacial complex" and affects other components of health and physical and mental wellbeing.[3]

The Oral Health-related Quality of Life (QHQoL) is defined as the individual's perceptions related to their health.[4] Its uses can include screening and monitoring for psychosocial problems in individual patient care, population surveys of perceived health problems, medical audits, outcome measures in health services or evaluation research, clinical trials, and cost-utility analysis.[5]

The Oral Health Impact Profile (OHIP) is based on the conceptual model proposed by Locker (1998),[6] which attempts to record the consequences of diseases at the functional level and their psychosocial involvement (Figure 1), in turn based on a model from the World Health Organization (WHO).[7]

For these analyses, measurement instruments have been developed that offer reliable and valid measures based on descriptions of human psychology.[8] QHQoL can be adversely affected by tooth decay and tooth loss, especially in young adults.[9] This is why the treatment of dental caries contributes to improved QHQoL.[10] Also, the preservation of teeth in older adults can improve body image and self-worth.[11] By this approach, the dentist can treat patients' oral problems and, at the same time, also offer integral treatment by considering the patients' self-perception about their oral health status.[10] Given that the QHQoL has an association with the oral clinical indicators,[12] it might also be affected by malocclusion.[13]

According to reports of the FDI, dental caries affect 44% of the global population and, if left untreated, can produce aches, difficulty in sleeping and eating, as well as having an impact on the growth of children. For these reasons, dental caries are a major cause of absenteeism (at schools and among the workforce).

In 15% of cases, dental caries progress to periodontal disease, ultimately resulting in tooth loss. Thirty percent of 65- to 74-year-olds have lost all of their teeth because of periodontal illnesses.[1] To compare the state of oral health between countries, the WHO recommends applying the DMFT Index to all 12-year-olds. By this approach, Paraguay is ranked as having an intermediate level of dental caries.[14]

Oral health has been advanced by the introduction of quality of life measurements, however, these measuring instruments have been developed and validated in diverse countries. There is an urgent need to fit instruments for oral quality of life to target populations, especially in Latin American countries.[15] Among these measurement instruments there is the OHIP, developed and validated by Slade in 1997 using 14 items.[6]

This questionnaire has seven dimensions: functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap, thereby measuring the negative aspects of oral health.[16] (Table 1)

In Paraguay, 63% of children between 11 and 14 years old self-perceived their oral quality of life as fair, 37% reported that problems with their teeth affected their daily activities.[17] While among older adults who lived in a state shelter, 71% had negative self-perception associated with the need for a lower prosthesis, medication use, lack of dental treatment, and gingival self-assessment.[18]

It is important to develop valid instruments for diagnosis, planning of the treatment, and prognostics, which will increase the adhesion of the patient or allow the treatment plan to be adjusted to meet the patient's perceptions, which will ultimately guarantee the success of the dental treatments.

The objective of this study was to culturally adapt and validate the short version of the Spanish OHIP-14Py questionnaire for Paraguayan adults.

MATERIALS AND METHODS.

Design

The study was cross-sectional, observational, and based on Classical Theory Test (TTC). The study was conducted in two phases:

Phase 1: Translation, examiner calibration, and pilot tests

We performed the forward-backward translation technique to Spanish from the original English language version. The semantics and construct were evaluated by a specialist in public health dentistry. Next, a Guarani version was produced, which was used when there was a lack of comprehension by the patient.

Two dentists were trained in the criteria of the WHO for the oral examination.[19] The Kappa's Index should be ≥0.80. Next, we conducted a pilot test consisting of 20 patients with similar characteristics to the study population, in which we evaluated the comprehension of the questions and carried out the necessary adjustments to the data collection sheets.

Phase 2: Validation of the psychometric properties of the OHIP-14Py

This phase included 333 adults and addressed the psychometric reliability and validity of the Spanish version of the OHIP-14Py.

Participants and setting

The data were collected during the first trimester of 2017. The study participants were adults of both sexes attending the Ministry of Public Health in the Republic of Paraguay (MSPyBS) establishments (Asunción and Paraguarí city) at the Dentistry Faculty of the National University of Asunción (FOUNA) and Community Center "Chacarita".

The inclusion criteria were: 18- to 59-years-old and Paraguayan (or foreign nationality with 15 or more years of residing in the country). We excluded those that did not wish to participate in the investigation, that spoke only Guarani, or whose level of comprehension of Spanish was insufficient.

For the calculation of the sample size, taking into account that the questionnaire contains 14 items and that the optimum number of subjects for the statistical analysis is about 20 for each item, it was necessary to include 280 subjects in the study. Accounting for a 10% loss of participants, we aimed to include 308 subjects. Following random sampling in the clinics of the university, and sampling of consecutive cases in the clinics of the ministry and the community center, the final study sample consisted of 333 participants.

Examiner Calibration

As there were two examiners, it was not necessary to perform the calibration in patients with the expert calibrator, in order to avoid false positives,[20] therefore the agreement of the examining pair was directly evaluated. The clinical calibration process was carried out on three occasions, until the result was values higher than 0.80 with the Kappa Index in all sections. The values obtained were 0.810 for dentofacial anomalies, 0.846 for soft tissues, 0.873 for dentition and 0.825 for dental prostheses.

Variables and source of information

The OHIP-14Py instrument was used to measure the QHQoL. The 14 items consisted of Likert scale responses ranging from "Never" to "Always" (assigned values of 0 to 4). High values indicate worse self-perception of oral health. Used weights recommended by Slade.[6]

To evaluate the oral health, the authors of this questionnaire considered the recommended gauges by the WHO for epidemiological studies[19] (Table 2).

The PCPUNC15 probes developed by HLW-Germany were used.[21] To evaluate the participant's self-perceived state of general health, we used the

Questionnaire of Health EuroQol-5D (EQ-5D-3D) of the EuroQol Research Foundation.[22]

This questionnaire contains five dimensions: mobility, personal care, daily activities, ache/malaise, and anxiety/depression. This questionnaire contains five questions with three options using a Likert scale (1 to 3 points). Moreover, a Visual Analog Scale (VAS, from 0 to 100) was used to record the participants' best imaginable health. The total score was calculated by summing the responses to the five questions and the VAS.

Statistical analysis

To analyze the psychometric properties of the instrument, we first carried out first an Confirmatory Factorial Analysis (CFA) using the generalized least squares method[23] to determine if the scores reproduce the multi-dimensional structure on which the original 14-item questionnaire is based.

Next, we evaluated the reliability using Cronbach's alpha. To evaluate the homogeneity between the items with the total score. The internal consistency was evaluated using the item correlation-total when each item was eliminated.

The discriminating validity was evaluated using the association between the total score of the OHIP-14Py and the dental states as evaluated by clinical examination, using the Mann-Whitney and Kruskal-Wallis tests.

Using Spearman's correlation, the convergent validity was evaluated based on the correlation between the total score of the OHIP-14Py and the score of each dimension with the self-assessment of oral health and DMFT Index. We also evaluated the correlation (Spearman's) between the OHIP-14Py and the EQ-5D-3L. In all cases, the statistical confidence level was 95%. For the data analysis, we used the IBM SPSS program (Statistical Package for Social Science) version 22.0 and .the EQS® program (Structural Equation Modeling) versión 6.1 for the CFA.

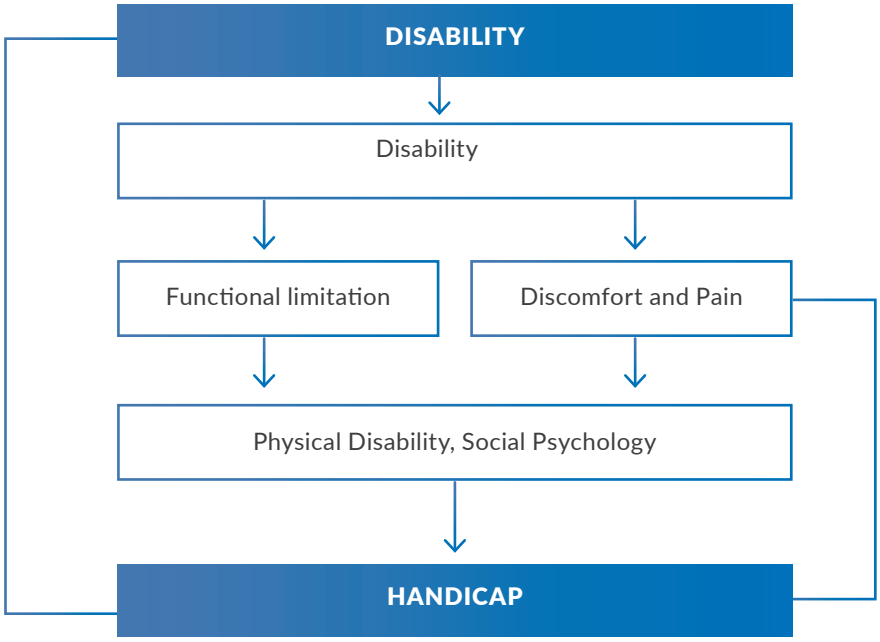
Ethical considerations

The autonomy of the person was respected at all time, with the participants being free to participate or being able to withdraw from the study without this affecting their care in the institution.

Sufficient information about the study and the researchers were provided to all participants for any subsequent need.

The data collected was kept confidential and the results presented as a whole. No subject was discriminated against for any reason, such as their race, religion, or other characteristics. Permission was requested from the corresponding authorities for the study execution following the usual procedures of the country.

Figure 1. Conceptual model adapted from Locker on oral health.[5]



RESULTS.

The study sample consisted of 333 patients (77.2% female, 22.8% male) with an average age of 34.9 years (standard deviation (SD) = 12.6).

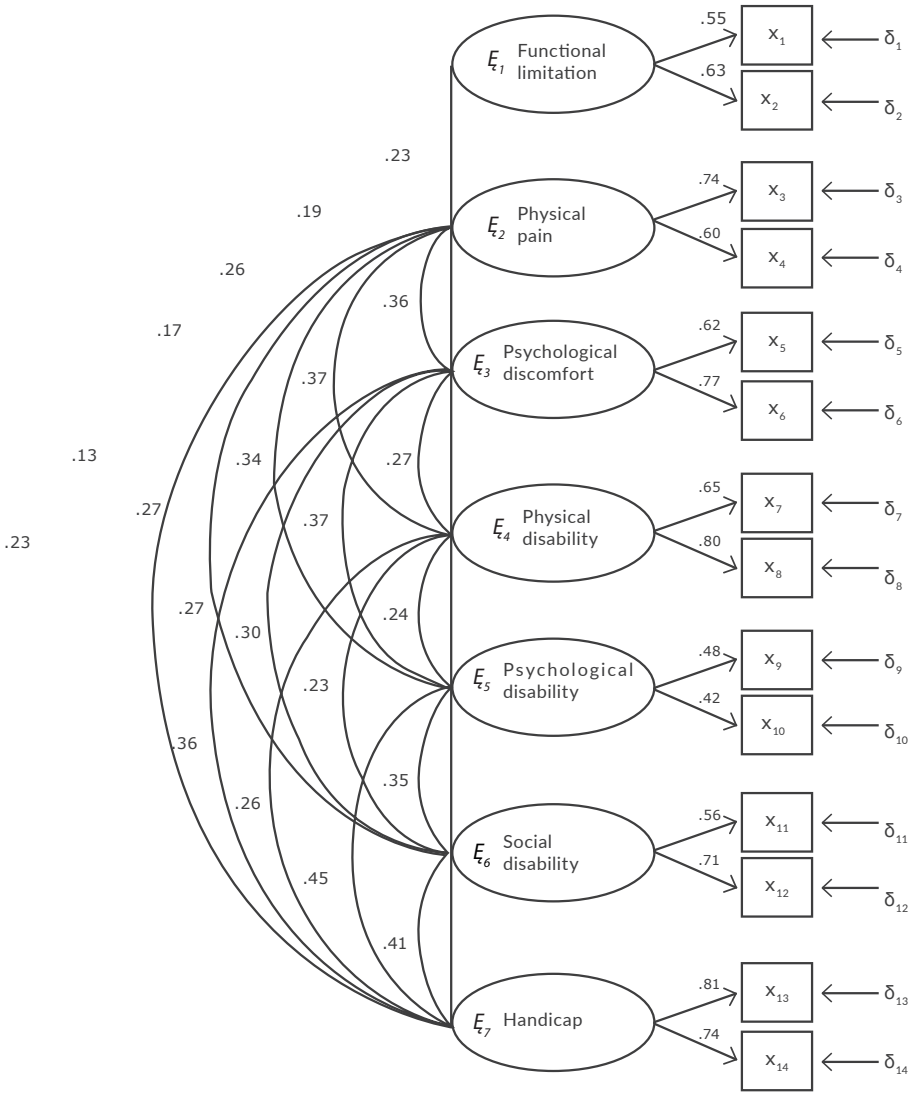
The factor structure was analyzed using a confirmatory factor analysis in which a model with seven domains was proposed (Figure 2).

The chi square test was statistically significant, but the adjustment ratio was 4.3 (between 2 and 6), suggesting that the fit is reasonably good. Likewise, both the rest of the absolute adjustment indices, as well as the incremental and parsimony adjustment analyzed, have the same tendency, it can be concluded the model is adjusted goodness.

Cronbach's alpha returned a value of 0.861. Comparing the values of the global Cronbach's α coefficient with the α coefficients when each element is eliminated, it is observed that none increases when an element is eliminated (Table 3). The corrected item-total correlation was greater than 0.35 for all items. When applying the discriminating analysis, it was statically significant when having ≥20 teeth healthy, symptoms of the temporomandibular joint (TMJ), self-assessment of oral health status, need for upper and lower dental prostheses (Table 4).

When evaluating convergent validity, all bivariate correlations for dimension were statistically significant for the self-assessment oral health state and the DMFT

Figure 2. Standardized model parameters.



CFI=.967:RMSEA=.052
Compartive Fit Index: RMSEA, Root Mean Standard Error of Approximation

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Table 1. Profile Impact Oral Health Index (original version with 14 questions).

Dimensions	Question	Weight
Functional limitation	Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?	0.51
	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	0.49
Physical pain	Have you had painful aching in your mouth?	0.34
	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	0.66
Psychological discomfort	Have you been self-conscious because of your teeth, mouth or dentures?	0.45
	Have you felt tense because of problems with your teeth, mouth or dentures?	0.55
Physical disability	Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	0.5.2
	Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	0.48
Psychological disability	Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	0.60
	Have you been a bit embarrassed of problems with your teeth, mouth or dentures?	0.40
Social disability	Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	0.62
	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	0.38
Handicap	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	0.59
	Have you been totally unable to function because of problems with your teeth, mouth or dentures?	0.41

*: Responses are made on a 5-point scale. Coded: 0=Never. 1=Hardly ever. 2= Occasionally. 3=Fairly often. 4=Very often. Within each dimension, coded responses can be multiplied by weights to yield a subscale score.

Table 2. Operational definition of variables.

Variables	Definition	*p*-values
Extraoral exam	The presence of lesions outside the oral cavity, on the head and lips is examined.	Normal extraoral appearance. Abnormal extraoral appearance: Ulcers, inflammations, erosions, fissures in the nose, cheeks, chin, corners of the lips or vermilion border. Anomaly of the upper or lower lips. Other swelling of the face and jaw.
DMFT index	Index used in epidemiological studies that measures parts affected by caries. To obtain the DMFT Index for the experience of caries among our study population, we collected data for decayed teeth (D), missing teeth (M), and failed teeth (F) per teeth unit (T) per patient.	It is obtained from the sum of decayed, lost and filled teeth; divided by the total number of individuals who participated multiplied by 100; 28 teeth were considered It was evaluated by level of severity: 1 to 3 = Very low 4 to 10 = Low 11 to 20 = Medium 21 to 28 = High

Variables	Definition	*p*-values
Dental prosthesis situation	Evaluate prostheses, if any, upper and lower, taking into account what the patient reports regarding their use.	Use: Yes/No
Need for dental prosthesis	It evaluates the need for a partial removable prothesis or a complete upper and lower dental prosthesis, taking into account what the patient reports regarding its use.	Need for prosthesis: None Unitary (uni- or bilateral) Multi-unit Unitary and multi-unit Complete
Dentofacial abnormalities	Dental malocclusion severity and need for treatment are observed according to the Dental Aesthetic Index (DAI).	The regression equation used to calculate the IED is as follows: (Visible teeth missing x 6) + (crowding) + (separation) + (diastema x 3) + (maximum anterior maxillary irregularity) + (maximum anterior mandibular irregularity) + (anterior superposition of the maxilla x 2) + (anterior superposition of the mandible x 4) + (vertical anterior open bite x 4) + (anteroposterior molar relation x 3) + 13. Resulting in the following levels: No mild malocclusion abnormalities; unnecessary or not necessary (≤25). Manifest malocclusion; optional (26 to 30). Severe malocclusion; highly desirable (31 to 35). Very severe or disabling malocclusion; mandatory (≥36).
Functional dentition	If there is minimal dentition for masticatory function	Yes: >20 teeth present (10 to 12 functional occlusion units). No: 20 teeth present.
Healthy Teeth	Natural teeth present in the mouth that did not receive or need any type of treatment and are completely healthy	0 to 19 healthy teeth. ≥20 healthy teeth.
Molar relationship	Determines the anteroposterior relationship of the first permanent molars	Normal Semi Cusp Full cusp
Status of the Temporoma ndibular Joint	Evaluation of TMJ assessing signs and symptoms present	symptoms : Yes/No Signs: Audible click, Pain on palpation, Reduced mobility (<30mm or two fingers)
Oral mucosa status	Lesions in the jugal, palatal, labial or lingual mucosa of the oral cavity, with various characteristics that can be differentiated by their clinical appearance.	No lesions: normal appearance Lesions: White lesion Ulcer Fistula Tumor Others, not registered
Self-perceived oral health status	How does the patient rate the general state of their oral health?	Excellent, Very Good and Good = Positive Regular = Neutral Bad = Negative

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Table 3. Descriptions obtained by suppressing each item of the OHIP-14Py. Paraguayan adults, 2017.

Element	Average scale with suppressed item	Variance scale with suppressed item	Corrected total element correlation	Multiple squared correlations	Cronbach's alpha when item is deleted
1	10.70	99.191	0.358	0.182	0.859
2	10.64	98.220	0.399	0.303	0.857
3	9.79	91.204	0.566	0.445	0.849
4	9.66	92.400	0.463	0.380	0.855
5	9.89	89.644	0.550	0.385	0.850
6	10.00	86.892	0.666	0.507	0.842
7	10.22	90.883	0.490	0.382	0.854
8	10.09	88.416	0.598	0.468	0.846
9	10.37	92.180	0.537	0.411	0.850
10	9.78	91.631	0.446	0.398	0.857
11	10.54	94.737	0.489	0.330	0.853
12	10.70	94.548	0.588	0.513	0.849
13	10.53	92.328	0.602	0.519	0.847
14	10.83	98.197	0.481	0.479	0.855

Table 4. Discriminant analysis of the OHIP-14Py. Paraguayan adults, 2017.

Variables		OHIP-14Py Average (SD)	Test
Healthy teeth	0 a 19	6.3 (5.6)	
	≥ 20	4.2 (4.3)	p=0.0011*
Symptoms of the TMJ	Yes	6.5 (5.2)	
	No	5.3 (5.2)	p=0.0261*
Self-assessment of oral health states	Bad	10.4 (6.8)	p<0.0012*
	Regular	6.2 (4.7)	
	Good	4.7 (4.4)	
	Very good	3.1 (4.1)	
	Excellent	4.3 (4.4)	
Need for upper dental prosthesis	No	4.7 (4.6)	p=0.0012*
	Unilateral unitary	4.5 (4.3)	
	Bilateral unitary	7.3 (5.7)	
	Multiunit	7.6 (5.8)	
	Unitary + Multiunit	6.1 (9.0)	
	Dentures	7.2 (5.8)	
Need for lower dental prosthesis	No	4.0 (4.0)	p<0.0012*
	Unilateral unitary	5.1 (4.2)	
	Bilateral unitary	8.6 (7.2)	
	Multiunit	5.8 (5.7)	
	Unitary + Multiunit	4.8 (5.0)	
	Dentures	3.5 (4.3)	
Molar relationship (n=274)	Normal	10.5 (10.3)	p=0.5092
	Semicus	12.8 (11.5)	
	Full cus	10.1 (8.3)	

Variables		OHIP-14Py Average (SD)	Test
Severity level of DMFT Index	Very low	6.1 (6.2)	*p*<0.0012*
	Low	9.7 (9.6)	
	Medium	12.2 (10.8)	
	High	16.9 (11.8)	
Use upper dental prosthesis	Yes	12.8 (11.2)	*p*=0.0041*
	No	9,42 (9,21)	
Use lower dental prosthesis	Yes	12.8 (1.01)	*p*<0.0011*
	No	7.9 (7.9)	
Severity levels of dental aesthetic index	Normal or minor Malocclusion	9.7 (8.9)	*p*=0.6272
	Definite malocclusion	10.9 (10.8)	
	Severe malocclusion	10.7 (10.0)	
	Very severe (handicapping) Malocclusion	12.2 (10.8)	
Click at TMJ	Yes	10.8 (9.9)	*p*=0.8661
	No	11.2 (10.7)	
Pain on palpation of the TMJ	Yes	12.0 (8.6)	*p*=0.1911
	No	11.0(10.5)	
Reduced mobility of the TMJ	Yes	14.4 (10.7)	*p*=0.1771
	No	10.6 (10.2)	
Oral mucosal lesion	Yes	11.4 (10.7)	*p*=0.0201*
	No	10.6 (10.2)	
Extraoral aspect	Normal	14.8 (13.2)	*p*=0.1271
	Abnormal	10.8 (10.0)	
Functional dentition	Yes	9.6 (9.4)	*p*<0.0011*
	No	15.1 (11.8)	

***:** Statically significant. **SD:** Standard Deviation. **TMJ:** Temporomandibular Joint.

Table 5. Convergent validity of the OHIP-14Py by subscales according to oral health self-perception and the DMFT Index of the OHIP14-Py. Paraguayan adults, 2017

OHIP-14Py		Self-assessment of oral health				DMFT Index
Subscales	Average (SD)	Positive (n = 87) Average (SD)	Neutral (n = 106) Average (SD)	Negative (n = 140) Average (SD)	Spearman's Rho	Spearman's Rho
Functional Limitation	0.775 (1.533)	0.5632 (1.361)	0.6321 (1.369)	0.727 (1.717)	0.482*	0.190*
Pain	2.667 (2.262)	1.8621 (1.862)	2.660 (2.251)	3.1714 (2.363)	0.746*	0.053*
Psychological discomfort	2.228 (2.456)	1.3448 (1.910)	1.8774 (2.275)	3.0429 (6.991)	0.795*	0.224*
Physical disability	1.802 (2.529)	1.2759 (2.122)	1.6226 (2.486)	2.2643 (2.721)	0.704*	0.127*
Psychological disability	1.964 (2.131)	0.9195 (1.391)	1.6226 (2.486)	2.2643 (2.721)	0.697*	0.296*
Social disability	0.871 (1.749)	0.5682 (1.36)	0.6226 (1.305)	1.2357 (2.155)	0.627*	0.161*
Handicap	0.751 (1.704)	0.5172 (1.627)	0.3585 (1.122)	1.1929 (1.100)	0.625*	0.303*

Table 6. Final version in Paraguayan Spanish.

Perfil de Impacto de Salud Oral" (OHIP-14Py)
En los últimos 6 meses, por causas de problemas con tus dientes, boca o dentadura/paladar/prótesis
1. ¿Tuviste inconvenientes para pronunciar palabras?
2. ¿Dejaste de disfrutar del sabor de los alimentos?
3. ¿Tuviste dolores en la boca o en los dientes?
4. ¿Sentiste incomodidad al comer algún tipo de alimento?
5. ¿Te sentiste inseguro?
6. ¿Te sentiste nervioso?
7. ¿Dejaste de comer algo?
8. ¿Tuviste que interrumpir las comidas?
9. ¿Tuviste dificultad para descansar?
10. ¿Tuviste vergüenza?
11. ¿Te pusiste nervioso con otras personas?
12. ¿Tuviste dificultades para realizar actividades diarias?
13. ¿Sentiste que tu vida empeoró?
14. ¿Te impidió realizar actividades diarias?

Opciones de respuesta: 0= Nunca. 1= Casi nunca. 2= A veces. 3= Casi siempre. 4= Siempre.

Index (Table 5). The total score of the self-perception of general health using the EQ-5D-3L was correlated with the OHIP-14Py score (r=0.251; p<0.001). The mean sum OHIP-14Py was 11.06 (SD=10.32), minimum was 0, the median was 8, and the maximum was 54 and the mean additive OHIP-14Py was 5.5 (SD=5.2) while the minimum was 0, the median was 4, and the maximum was.[27] Table 6 presents the Paraguayan Latin American Spanish version of the OHIP-14Py.

DISCUSSION.

The objective of the study was to develop the Paraguayan version of the OHIP-14 by cultural adaptation of the English language version while retaining its psychometric properties.

Difficulty was found in understanding the questions due to loss of concentration due to the length of the questions, so it was decided to follow a reduced format, where a main statement was placed and the fourteen questions were shortened.

Regarding the form of administration, questionnaire or interview, it has been found that it does not influence the total scores of the OHIP. However, the interview presented a significantly higher response rate, which is why in this study we opted for a face-to-face interview method with the patient.[24]

It is under debate whether the structure of the questionnaire is multidimensional or unidimensional. Currently, several studies suggest that the OHIP-14 has a one-dimensional structure, and its description using the total scores is adequate. The multidimensional criterion was considered in this study, taking into account that most of the validation studies considered seven dimensions of the instrument.[25-36]

Next, the reliability of the instrument was evaluated using Cronbach's α coefficient. To evaluate the homogeneity between the items, the global behavior of the scale was found, which was 0.861 for this study, interpreted as very good and indicative that there is homogeneity between the items on the scale.[37] This value was slightly lower than the 0.88 obtained in the original English version.[16]

The internal consistency was evaluated by means of the item-total correlation when an item was deleted, considering values above 0.80 to be adequate, because the test is considered to have a diagnostic or classification purpose 38 and less than 0.90 since higher values are a sign that there is redundancy or duplication 39. It was observed in this study that no value increased when eliminating an element, with the range from 0.846 to

0.849, which is satisfactory as it indicates homogeneity, similar to the results obtained in other studies where even lower values were obtained.[25,30,31]

The EQ-5D-3L was correlated with the OHIP-14Py score (rho = 0.3), and this was more positive than in a study in Australians adults (rho = -0.4).[40]

In oral health among New Zealand adults, OHIP-14 scores were significantly associated with clinical oral health status indicators, independently of sex and socioeconomic inequalities.[41]

The mean additive OHIP-14 score was 18.9 (SD 13.6) for patients attending a Primary Care Department at a London dental hospital,[42] which is higher than the value obtained in our study.

The sample only covers two health regions and the non-inclusion of indigenous populations, which is why it would not be prudent to extrapolate to the entire population. However, the sample could be considered representative in terms of social strata, given that it includes a very socio-economically disadvantaged sector such as the Ricardo Brugada neighborhood known as "La Chacarita". The patients who came to FOUNA are from different parts of the country, and come due to the affordable costs and good referrals, as well as the patients who came from the Pirayú health center who reside in the interior of the country, where there are very few private dental offices. There is inequity in access to health services.

The questionnaire was only validated in adults, therefore, it is not yet applicable in a reliable and valid way in other population groups. On the other hand, it should be noted that the results may constitute a national reference regarding the oral health status of the Paraguayan adult population, since there are no other reports for the adult population since 1974.

CONCLUSION.

The Spanish version of the questionnaire was reliable in terms of internal consistency. Cronbach's alpha was adequate for the global score and for the seven domains of the OHIP-14Py. The convergent validity of the OHIP-14Py questionnaire showed a correlation of the seven domains with self-perception of oral health, the CPO-D index and the VAS visual analog scale.

The discriminant validity showed a relationship between the OHIP-14Py questionnaire score with the perception of the state of oral health, having less than twenty healthy teeth, perceiving some discomfort in the TMJ, needing and being a carrier of both upper and lower prostheses, the presence of lesions in the oral mucosa and not presenting a functional dentition. The construct validity was confirmed by obtaining a reasonably good fit with the confirmatory factor analysis.

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