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Assessing the conceptual model of the Oral Health Impact Profile-49 (OHIP-49): A path analysis

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Objective: To assess the fit between of the Romanian version of the Oral Health Impact Profile (OHIP-49) and Locker's conceptual model of oral health. ***Basic research design:*** Cross-sectional interview study. ***Clinical setting:*** Convenience sample of hospitalized internal medicine patients, in Cluj-Napoca, Romania. ***Participants:*** 340 participants (40% male), divided in two samples, sample N1 = 165 to analyse the theoretical model, and a cross-validation sample, N2 = 175. ***Main outcome measures:*** Path-analysis was used to assess the fit between the conceptual model proposed by Locker, and the data. ***Results:*** Initial results showed an unsatisfactory fit to the data: $\chi^2 = 43.8$ (df = 5, p = 0.001), χ^2 was found to be significant; GFI = 0.932, CFI = 0.948, TLI = 0.782, these indices presented values lower than 0.95, while SRMR = 0.053 and RMSEA = 0.22 (90% CI 0.16 – 0.28) were situated above the accepted threshold. Evaluation of the residual matrix and the modification indices lead to the respecification of the first model, obtaining an better fit of the second model: $\chi^2 = 17.63$ (df = 9, $p = 0.04$), while GFI = 0.972, CFI = 0.988, TLI = 0.973, were above the threshold and SRMR = 0.036 and RMSEA = 0.07 (90% CI 0.02 – 0.12). ***Conclusions:*** The current study indicates that OHIP-49 represents an acceptable operationalization of the Oral Health related Quality of Life, as it was conceptualized by Locker's theoretical model.

Keywords: *Quality of life, OHIP-49, path-analysis, conceptual validation*

Introduction

Oral Health related Quality of Life (OHRQoL) represents a multidimensional construct, comprising various aspects of oral health (Baker *et al.*, 2008). The World Dental Federation defines OHRQoL as a fundamental component of health, underlining its multifaceted character, including elements such as the ability to exercise the physical oral functions (speaking, chewing, tasting, swallowing) or to assert emotions through facial expressions, in the absence of pain, discomfort or disease, within the cranio-facial complex (Glick *et al.*, 2016). OHRQoL is measured by specific self-report instruments (Slade, 1997a), one of the most elaborated of which is the Oral Health Impact Profile-49 (OHIP-49), developed by Slade and Spencer (Slade and Spencer, 1994; Slade, 1997a), and based upon Locker's (1988) conceptual model of oral health. Locker's original model, derived from the World Health Organization's (1980) classification of disease impacts, regards oral health as a causal model comprising *disease*, *impairment*, *functional limitation*, *discomfort*, *disability* and *handicap* (a detailed definition of each concept can be assessed in Locker, 1988).

OHIP-49 is based on a slightly modified version of Locker's model. The *functional limitation* and *handicap* dimensions remain unchanged, while *pain* and *psychological discomfort* become two distinct dimensions replacing *discomfort*. The initial concept of *disability* was redefined as three distinct dimensions of *physical*, *psychological* and *social disability*. The conceptual model of OHIP-49 does not include the original *disease* and *impairment* dimensions (Baker *et al.*, 2008; Slade and Spencer, 1994) (Figure 1).

OHIP-49, together with its shortened, OHIP-14 (Slade, 1997b) or modified forms have been adapted in various countries (John *et al.*, 2002; Grecu *et al.*, 2015; van der Meulen *et al.*, 2008) and successfully used in clinical research to measure the functional, psychological and social outcomes of oral disorders. Studies have targeted participants of differing status, including pregnancy (Geevarghese *et al.*, 2017), oro-facial pain (Shueb *et al.*, 2015) and temporomandibular disorders (Yule *et al*., 2015).

The widespread use of OHIP-49 is based on its psychometric properties (John *et al*., 2014a). However, the measure has recently been interrogated in methodological studies to assess its factorial and conceptual validity (John *et al*., 2014a, 2014b).

Conceptual validity can be investigated by assessing if the model can predict inter-item correlations. That is, if the dimensions of OHIP-49 correspond to the stages in the Locker model, so that if the model is correct, dimensions should correlate in the way predicted by the model. Such research remains limited at present. Nuttall and colleagues (2006) tested the ability of the

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model to predict response combinations, using four dimensions of OHIP-14 obtained by combining the existing dimensions. Some direct paths were eliminated from the original Locker model (functional limitation-disability and functional limitation-handicap) and others were added (functional limitation-pain/discomfort, pain/discomfort-handicap). Despite this respecification, the authors concluded that the findings gave strong conceptual support for the OHIP-14.

Baker (2007) used path analysis to assess the conceptual validity of OHIP-14. The original model does not distinguish between discomfort and pain, whereas OHIP scores each separately. Baker addressed this conceptual issue by introducing a direct path between pain and discomfort, thus, slightly modifying the original model. The results provided further support for Locker's conceptual model. In the most recent study, Baker and colleagues (2008), fitted Locker's model to OHIP-49 data using latent regression analysis. The analysis did not support the conceptual validity of OHIP-49 because many of the direct effects of the original model did not correlate. However, other newly formulated paths, improved the global fit of the model to the data.

The factorial structure of OHIP has also been debated. Research on the cross-cultural replication of the factorial structure is limited with few studies investigating the original factorial structure using exploratory or confirmatory factor analysis (Zucoloto *et al.*, 2014; Grecu *et al.*, 2015).

The conceptual model has only been investigated using the original English language version of OHIP. These assessments resulted in slight modifications of the initial model. The literature does not provide information on the cross-cultural generalisability of the model. Therefore, the aim of this study was to test the fit between the dimensions of the Romanian version of OHIP-49 and Locker's conceptual model of oral health, using structural equation modelling for path analysis. It was anticipated that the findings could contribute to the understanding of the generalisability of the conceptual model and validate the Romanian version of OHIP-49 for use in that country.

Method

The original version of OHIP-49 (Slade, 1997a) contains 49 items, distributed into seven conceptual dimensions. Participants report the frequency of experiencing a specific impact within the last 12 months on pre-coded five-point Likert scales ranging from "never" (0) to "very often" (4). This study used the validated Romanian version of OHIP-49 (OHIP-49Ro) (Grecu *et al.*, 2015).

Permission was obtained from the Ethics Committee of the "IuliuHaţieganu" University of Medicine and Pharmacy (Certificate No. 452/2015), Cluj-Napoca and all participants gave informed consent. The questionnaire was administered as a structured interview. Scores were computed according to literature guidelines (John *et al.*, 2002).

Participants were a convenience sample of 340 patients admitted to the Second Medical Clinic of Internal Medicine, Cluj-Napoca, Romania. The initial sample was randomly split in two subsamples: sample N1 = 165, to analyse the theoretical model, and N2 = 175 used for a cross-validation. The sample size was selected to reflect the number of freely estimated parameters Kline (2005).

Data analysis first examined the distributions of variables to detect any violations of normality. Skewness and kurtosis were assessed using cut-offs proposed by Kline (2005). Potential multicolinearity was assessed using Pearson correlations and the variance inflation factor (VIF). All descriptive statistical analyses employed the IBM SPSS version 23 software (IBM Corp., 2015).

Path analysis was used to test the relationships (direct and indirect) hypothesised between the constructs of Locker's (1988) theoretical model. Direct effects were estimated using Maximum Likelihood (ML), while the ML bootstrap estimation approach (standard error and 90% Confidence Interval) was applied to estimate indirect effects. Goodness-of-fit was assessed with Chi-square (χ^2), the General Fit Index (GFI) (Bentler, 1990), the Comparative Fit Index (CFI), the Tucker-Lewis Index (TLI) (Tucker, 1973), the Standardized Root Mean Square Residual (SRMR) (Hu and Bentler, 1998), and Root Mean Square Error of Approximation (RMSEA) (Bentler, 2007). The critical cut-off point for all indices respected the recommendations in the literature (Hu and Bentler, 1998; Bentler and Bonett, 1980).

The theoretical model was analysed in Sample 1, using model trimming (deleting non-significant paths) and construction strategies (adding non-hypothesized paths, based on the modification indices and theoretical sound-

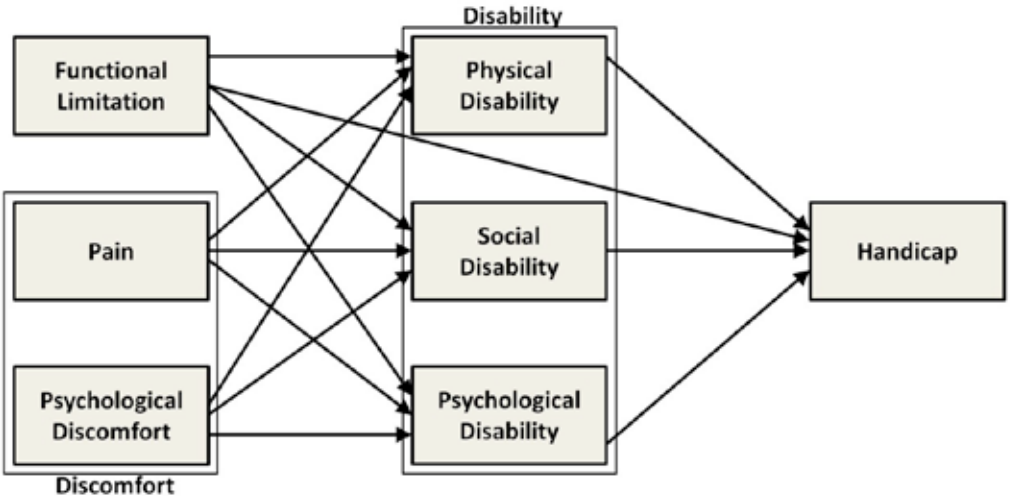

Figure 1. *Locker's model reflected in the OHIP-49 factors*

ness) (Kline, 2005). The respecified model was cross validated in an independent sample (Sample 2), which was selected from the same population, applying the same selection method. All the analyses were conducted with the IBM AMOS 23 software (Arbuckle, 2014).

Results

Of the 340 participants, 60% were female and 40% male. The mean age was 54.1 years (range 18-89 years) and education levels ranged from middle school to PhD.

Means, standard deviations, bivariate correlations and alpha coefficients of the measures used in the path model, are shown in Table 1. The absolute values of skewness and kurtosis, for all variables, were below the recommended cut-off and therefore considered not to violate the assumption of univariate and multivariate normality (Kline, 2005). VIF values were also below the established methodological cut-off.

All the correlations between variables predicted by the model were positive and statistically significant (Table 2).

Path analysis using the ML approach tested the relationships hypothesised Locker's theoretical model in Sample 1. The model contains three main steps through which oral impairment could handicap an individual's normal role function (Figure 1). Functional limitation and pain/psychological discomfort are proximal causes of disability. Handicap is determined directly only by disability and functional limitation.

The hypothetical model did not show an acceptable fit to the data: $\chi^2 = 43.8$ (df = 5, $p = 0.001$), χ^2 was found to be significant; GFI = 0.932, CFI = 0.948, TLI = 0.782, all the three presenting values lower than 0.95, while the values for SRMR = 0.053 and RMSEA = 0.22 (90% CI 0.16-0.28) were higher than the accepted threshold.

Many paths were not found to be significant, including those between functional limitation and psychological disability, functional limitation and social disability and between functional limitation and handicap. A direct effect was not evident between pain and social disability, between psychological discomfort and social disability or between psychological disability and handicap (all $p > 0.05$).

All the non-significant paths were deleted. Based on analysis of the standardised residual matrix and of the modification indices, the model was respecified, by adding new paths, using their statistical contribution to improve model fit and their theoretical soundness. As such, direct effects between physical disability and psychological disability and from psychological disability to social disability were introduced (dotted lines mark the added paths). With these modifications, the initial model was respecified, and the path analysis repeated (Figure 2). As a consequence, the fit indices reached an acceptable level: $\chi^2 = 23.73$ (df = 9, $p = 0.005$) was found to be still significant, but the other fit-indices were above (or below) the threshold values: GFI = 0.964, CFI = 0.984, TLI = 0.962 and SRMR = 0.038. The root mean square error of approximation value was situated above the established threshold of a good fit (RMSEA =

Table 1. Means, standard deviations, skewness and kurtosis of the variables used in this study

			Mean	*Standard deviation*	*Skewness*	*Kurtosis*	*Cronbach's α*
Sample 1 (N=165)	1.	Functional Limitation	1.17	0.81	0.9	0.42	0.749
	2.	Pain	1.12	0.88	1.03	0.60	0.862
	3.	Psychological Discomfort	1.09	1.15	0.87	-0.35	0.913
	4.	Physical Disable	0.78	0.85	1.32	1.16	0.87
	5.	Psychological Disable	0.74	0.88	1.33	1.12	0.896
	6.	Social Disable	0.40	0.66	2.2	5.41	0.87
	7.	Handicap	0.36	0.61	2.19	5.02	0.835
Sample 2 (N=175)	1.	Functional Limitation	1.17	0.86	0.89	0.24	0.794
	2.	Pain	1.14	0.86	1.09	- 0.23	0.848
	3.	Psychological Discomfort	1.12	1.13	0.89	0.89	0.9
	4.	Physical Disable	0.74	0.81	1.33	1.12	0.849
	5.	Psychological Disable	0.76	0.84	1.19	0.61	0.848
	6.	Social Disable	0.39	0.6	1.92	3.69	0.774
	7.	Handicap	0.34	0.55	2.23	5.45	0.756

Table 2. Correlation matrix for dimensions of OHIP-49Ro ($N_1 = 165$ and $N_2 = 170$)

		1	*2*	*3*	*4*	*5*	*6*	*7*
1.	Functional Limitation	1	0.77	0.57	0.71	0.56	0.35	0.32
2.	Pain	0.74	1	0.62	0.75	0.68	0.47	0.46
3.	Psychological Discomfort	0.56	0.59	1	0.68	0.67	0.44	0.5
4.	Physical Disability	0.69	0.72	0.66	1	0.67	0.42	0.41
5.	Psychological Disability	0.57	0.65	0.73	0.7	1	0.62	0.58
6.	Social Disability	0.41	0.49	0.57	0.54	0.71	1	0.69
7.	Handicap	0.44	0.51	0.56	0.53	0.63	0.75	1

** data for sample N_1 are below the main diagonal, and for sample N_2 are above the diagonal*

0.09 (90%CI 0.02-0.12). As the chi-square is influenced by sample size, and because RMSEA was higher than the threshold value, but still in the range of an acceptable fit, the conditions of a good fit between the model and the data were met. Standardized direct and indirect effects and the total effects are presented in Table 3.

Cross-validation was achieved by assessing the generalisability of this new model to the second (N2) sample was used. The model was specified based on the results of the previous path analysis. We found a significant chi-square, $\chi^2 = 17.63$ (df = 9, $p = 0.04$), while GFI = 0.972, CFI = 0.988, TLI = 0.973, were above the threshold. SRMR = 0.036 and RMSEA = 0.07 (90% CI 0.02-0.12), were below the threshold. All the results indicated a good fit of the model to the data. Standardized direct and indirect effects, and the total effects estimated for Sample 2 are presented in Table 3.

Discussion

Self-report instruments are used to measure the subjective experience of oral conditions (Alzarea, 2016; Bugone *et al*., 2019), and can link this experience with clinical data, within the frame of evidence based dental practice (Yamaga *et al.*, 2019). Consequently, recent decades have seen a growth in the use of self-report instruments in oral health research (Oghli *et al.*, 2017). This use requires empirical research support, both from a conceptual viewpoint (the validation of the theoretical model) and a psychometric one (reliability, validity). The purpose of the current study was to provide new evidence on the conceptual foundation of the most frequently used OHRQoL measure, particularly regarding the cross-cultural generalisability of the theoretical model underpinning OHIP-49. Thus, this study investigated Locker's (1988) conceptual model and to determine the extent, to which the relations between the dimensions of OHIP-49 reflect the relationships specified within that model.

Earlier research testing this conceptual model has derived new versions of it.

The results of this study offer partial support for Locker's conceptual model, adding supplementary details to it: i) functional limitation was linked directly only to the physical aspects of disability and was not related to psychological and social disability; ii) pain was related to both physical and psychological disability but not to social disability; iii) psychological discomfort was also related to physical and psychological disability but not social disability; iv) handicap was predicted only by physical and social disability (the revised Locker model is presented in Figure 3).

Another finding supports the relationship between the three disability dimensions of OHIP. Direct paths were found between physical and psychological disability and between psychological and social disability. These findings have a strong exploratory character, being included in the model, following the inspection of the modification indices (MIs). Even though these paths were confirmed through a cross-validation study, further research is needed to identify their specific role in OHRQoL.

Results that appear to contravene Locker's model are the absence of direct effects between functional limitation and handicap and between psychological disability and handicap.

Interpretation of these results should take into consideration that Locker model is a *mediational*. Thus, the lack of a direct effect does not imply that the predictor has no effect upon the dependent variable. Indirect effects were present, such that functional limitation has an indirect effect upon handicap as indicated in Table 3.

These findings can be compared with those of similar studies. Baker's (2007) initial path analysis did not allow for the establishment of detailed relationships between the causal variables (functional limitation, pain and discomfort) and a mediator variable (disability), because of the use of a total score for disability (adding up all disability item scores). Moreover, whilst Baker's analysis supported the direct path between functional limitation and handicap, and this study did not, the estimated parameters for this effect were similar in both studies. Baker's large sample of 5268 may have yielded greater power to detect this effect as significant.

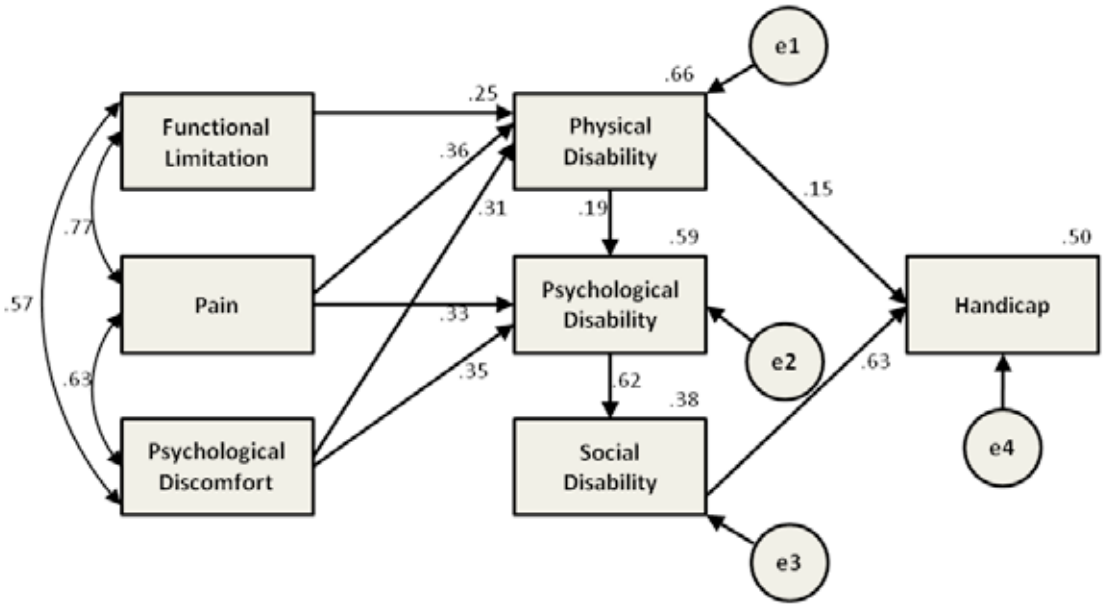

Figure 2. Direct path effects

Table 3. Standardized direct, indirect and total effects

		Sample 1 (N = 165)			*Sample 2 (cross-validation) (N = 175)*		
		Direct effect	*Indirect effect*	*Total effect*	*Direct effect*	*Indirect effect*	*Total effect*
1. Functional Limitation	→ Physical Disability	0.25**	-	0.25**	0.27**	-	0.27**
	→ Psychological Disability	-	0.05*	0.05*	-	0.09*	0.09*
	→ Social Disability	-	0.03*	0.03*	-	0.07*	0.07*
	→ Handicap	-	0.06**	0.06**	-	0.1*	0.1*
2. Pain	→ Physical Disability	0.36**	-	0.36**	0.34**	-	0.34**
	→ Psychological Disability	0.33**	0.07*	0.4*	0.12*	0.12*	0.24*
	→ Social Disability	-	0.25*	0.25*	-	0.19**	0.19**
	→ Handicap	-	0.21**	0.21**	-	0.19**	0.19**
3. Psychological Discomfort	→ Physical Disability	0.31**	-	0.31**	0.3**	-	0.3**
	→ Psychological Disability	0.35**	0.06*	0.41*	0.47**	0.12*	0.59**
	→ Social Disability	-	0.25*	0.25*	-	0.45**	0.45**
	→ Handicap	-	0.21*	0.21*	-	0.36**	0.36**
4. Physical Disability	→ Psychological Disability	0.19**	-	0.19**	0.35**	-	0.35**
	→ Social Disability	-	0.12	0.12	-	0.27**	0.27**
	→ Handicap	0.15**	0.07*	0.23*	0.18**	0.19**	0.37**
5. Psychological Disability	→ Social Disability	0.62**	-	0.62**	0.78**	-	0.78**
	→ Handicap	-	0.39*	0.39*	-	0.53**	0.53**
6. Social disability	→ Handicap	0.63**	-	0.63**	0.68**	-	0.68**

* $p < 0.05$
** $p < 0.01$

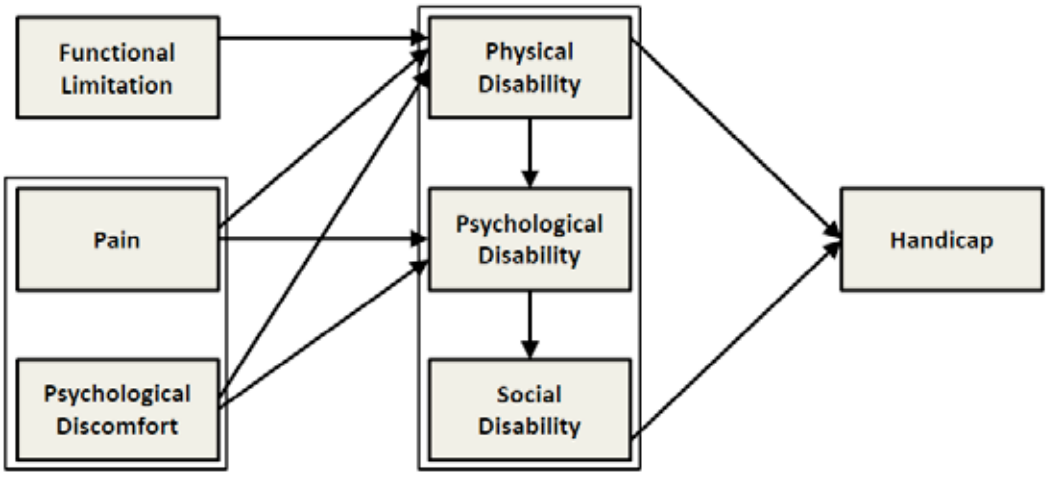

Figure 3. The revised Locker model

The second study (Baker *et al.*, 2008) using a full SEM procedure confirmed only one relation, between pain and psychological impact (psychological impact being a dimension obtained by combining items formally belonging to both the dimensions of psychological discomfort and psychological disability). However, Baker and colleagues respecified the factor structure of OHIP-49, eliminating some dimensions, reformulating others and either removing or reallocating items the newly reformulated dimensions. Consequently, our results cannot be directly compared with those provided of the full SEM applied by Baker.

Cumulatively, the results of studies testing the conceptual validity of OHIP (be it the long or reduced form), do not contradict Locker's model, rather they suggest further its respecification, allowing, more precise predictions. Both studies conducted by Baker and colleagues (2007, 2008) note that the inclusion of internal and circumstantial factors, inside the structure of Locker's model, would be desirable for future model testing.

The interpretation of these data should consider that the participants were recruited a hospital clinic. Medically compromised people are more susceptible to impaired oral health, possibly resulting in higher OHIP-49 scores. This would might create a possible ceiling effect, affecting the correlations between variable. There are no current national OHIP-49Ro representative standards, against which we can compare our results, but the inspection of skewness and kurtosis did not violate assumptions of normality, so supporting the correlations, and path coefficients. In any case, any such effects of the sample would be indirect as there were no questions related directly to general health in the interview. The relatively advanced age of the sample suggests that future model validation should include young adults of different educational and cultural backgrounds.

As non-clinical research, this study omitted two dimensions from the Locker model (impairment and disease), with the risk of model specification error (left out variables error) (Mauro, 1990). This can result in different estimates for the path coefficients. Therefore, to fully investigate its conceptual validity, the complete version of Locker's model should be tested, incorporating clinical measures of disease and impairment. Future research should also consider the direct and indirect causal relationships between these two dimensions and the other dimensions.

In conclusion, this study obtained a good fit of Locker's modified model to OHIP-49Ro, giving insight to the relationships between the model's dimensions, and the opportunity to refine the model, by adding possible missing causal elements. The data also offer further support for the conceptual validity of the Romanian version of OHIP-49, to assess oral health-related quality of life in that country.

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