Title: Validation of the Spanish version of the Oral Health Impact Profile (OHIP-14Sp) in elderly Chileans.

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Author's response to reviews: see over
RESPONSE LETTER TO REVIEWER’S COMMENTS

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We have carefully considered all the comments and suggestions from the reviewers. We appreciate the insights, as they have all served the purpose of improving the quality of this manuscript. Please find the modified text in the manuscript highlighted in yellow.

Reviewer’s comments

Referee 1, Reviewer: Simon Stone

1. Is the question posed by the authors well defined?

The study aim is outlined at the end of the “Background” paragraph. The authors should clarify if this is a prospective study or retrospective analysis of previously obtained data. In the aim it is unclear if the instrument will be developed as well as validated as part of this study.

R. We agree with the reviewer. A new sentence has been added by the end of the last paragraph in the background sentence. Likewise, we modified the methodology section to clarify the nature of the study for the development of the short instrument and also the source of patients for the validation study (please see Methodology, beginning of the first paragraph).

2. Are the methods appropriate and well described?

Inclusion and exclusion criteria should be clearly stated.

R. We clarify methodology section in the second paragraph adding inclusion criteria.

The terminology used “elder” can mean different things in different parts of the world depending on social normal values, consider using “older adult” throughout.

R. The modification has been done.

The details of the sample size calculation are unclear. How have you arrived at the total of 490 subjects? 10 subjects per question is stated but it is unclear why. Is this based on previous work, if so please reference or
did you carry out a formal sample size calculation to detect a particular difference in the population?

R. Sample size was actually calculated. The references used to obtain the sample size are now added in the Methodology section (see ref. 25-26).

The convenience sample provided a 70:30 ratio of females : males, is this representative of the adult Chilean population? How will you make sure that the findings are transferable?

R. The explanation for this issue has been added at the end of the last paragraph in the Discussion section.

Later in the methods you select a further 85 adults for correlation analysis. How did you arrive at this number, how did you choose these participants? If based on previous studies then please reference appropriately. How did you make sure that they were representative of the overall sample?

R. This has been clarified above (please see answer to Q. 1). In the methods sections we have stated that the sample was obtained from a previous study cited in the manuscript. We cannot, therefore, make sure the sample size represents the overall sample. We acknowledge this issue as a limitation of this study in the Discussion section (please see the beginning of the last paragraph).

The methods do not state how the OHIP-49sp was administered. Was it carried out verbally or written? If written, then were the participants able to read and understand the questionnaires (inclusion criteria)? If verbal then please clarify.

R. Details regarding the procedure of the OHIP administration are detailed in the third paragraph, methods section.

Did the authors consider any form of test re-test reliability of the newly developed questionnaire?

R. Although a test re-test is used sometimes, based on our good Cronbach’s score, we did not considered this approach, just as we did for the Chilean OHIP-49Sp validation study.

Further clarification of where the clinical and socio-demographic data has been obtained from is required, was this from the 490 in the OHIP-49Sp validation study or from your additional cohort of 85? It does not appear that it is from the same cohort of patients. Again is this study a retrospective analysis of the data from a previous study? Much of the results and discussion focuses upon the correlation between these data and the OHIP data, please be transparent where it has been obtained from.

R. The whole study design has been clarified in the Methodology section.

3. Are the data sound?

Noting the above, the OHIP data appears to have been obtained and managed appropriately. The authors have described their findings appropriately. The response rate is remarkably good (100% complete).
How was this quality of response rate ensured? If there were any missing data points how were these managed?

R. Sample size was calculated to be 490. We attended the centers to recruit the participants up to completion of the required number. Although most of the invited subjects accepted the invitation to participate, we did not keep track of the few that did not want to answer the survey. The latter explains why we obtained the good response rate.

Throughout the results the authors refer to OHIP “dimensions” in the original publication these should be described as “domains”.

R. The reviewer is correct and we have modified it in the text.

Tables:
There are 7 tables within this paper. The following were noted:

T1: Could be simplified by removing IQR columns.

R. The modification has been done.

T2: Is there a reason that the a dimension items are clearly listed in the left hand column but those denoted s are not?

R. No, the reviewer is right. We have deleted the “a” from the left column.

T5: Consider simplifying.

R. The table has been simplified, thank you.

T7: Would this be more appropriately written in the main text?

R. Table 7 was removed and the information was kept only in the main text.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

5. Are the discussion and conclusions well balanced and adequately supported by the data?

The discussion clearly links to the previous work and is appropriately referenced, conclusion is succinct and proposes potential future uses of the developed instrument.

6. Are limitations of the work clearly stated?

The limitations of sample size estimation are stated. The authors should consider the limitations of the statistical tests used.

R. We believe that the selection of the statistical tests used is the customary tests for this kind of study.
7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?

Yes. There is clear evidence here of building on previous work, the authors should be transparent from which sources the data is being used from as there are two distinct data sets being used. One is from previously published OHIP-49Sp and the other from a smaller cohort of 85 participants.

R. We have addressed this issue when responding to a previous query from the reviewer.

8. Do the title and abstract accurately convey what has been found?

The abstract is appropriate but should clarify the aim of the study to include development as well as validation of a short form OHIP-14Sp tool for use in an older adult population. Note the terminology “elder” will have different meaning depending on the social norms of a particular region. Consider using “older adult” (60 + years) as a more appropriate term.

R. These modifications have been done in each mentioned section.

9. Is the writing acceptable?

Yes the language used is appropriate and understandable; there are some minor typographical and grammatical errors which will no doubt be managed by the editorial team.

Referee 2, Reviewer: Mike John

The manuscript “Validation of the Spanish version of the Oral Health Impact Profile (OHIP-14Sp) in elderly Chileans” by Leon et al. describes the development of a 14-item version of the OHIP. Using the methodology that Slade used for the development of the original 14-item version, these authors developed an abbreviated instrument that is different from the standard OHIP-14.

Short OHIP forms are widely used. They are necessary tools to assess oral health-related quality of life (OHRQoL) in situations where limited resources don’t allow the use of the long instrument. OHIP-14 is probably the most popular OHRQoL instrument today. Validation of this instrument is required to understand how well it performs in different populations. Above and beyond this methodological point, it is interesting to use OHIP scores to express how oral conditions affect individuals in different settings.

One of the advantages of OHIP is that it is globally used, and researchers have compatible findings across nations and cultures. However, it is unfortunate that several different 14-item OHIPs exist already. Adding a new instrument now makes this situation worse because the existence of several OHIPs limits the comparability of findings. Although the authors’ intention was to create an instrument that would illicit globally comparable results, I believe the current authors’ new OHIP-14Sp does not create
internationally compatible scores because the questionnaire items are different compared to other OHIP-14 instruments.

R. Although we partially agree with the statement of the reviewer, we took the approach of validating the most relevant questions through the linear regression. Our decision was made on the ground that idiosyncratic issues of a given population may condition which questions result more relevant for oral health-related quality of life. Hence, we believe that the present study will contribute a relevant tool for the evaluation of the quality of life among the Chilean population.

Major Compulsory Revisions

The key to understanding the findings of the submitted article is OHIP’s dimensionality. While the authors mention an article which suggests that OHIP-14 score is unidimensional, I would recommend two articles that appeared in the Journal of Oral Rehabilitation (John et al., 2014) for a detailed insight into OHIP’s dimensionality. As these authors report, OHRQoL is multidimensional, but for OHIP, one summary score can also be used. If these findings are true, it is expected that several different OHIP-14 can be derived because all OHIP items are indicators of the construct OHRQoL. All these different OHIP-14s describe one construct and, according to classical test theory, only the idiosyncrasies of the particular sample result in the selection of a different set of items. If the current authors would compare their OHIP-14Sp with the standard OHIP-14, they would likely find that scores of the two instruments are not too different in terms of their reliability and validity. Only if the new OHIP-14Sp scores would make a clinically relevant difference compared to using the standard OHIP-14 scores, would a new OHIP-14 be justified.

R. We agree with the thorough discussion of the reviewer on this important issue. We are actually presenting a single final score to perform all our associations. We have considered the citations recommended by the reviewer and have incorporated them in the Discussion section.

I see substantial value in the validation of the STANDARD OHIP-14 in this population. If the authors assume that the standard OHIP-14 is unidimensional, the logical conclusion would be to present only one summary score. Although they are complex, tables 5 and 6 don’t provide any evidence that the 7-dimensional structure is valid. For example, one would expect that the number of teeth has a functional influence. If the 7 dimensions are useful, one should also see a differential impact (not in terms of statistical significance, but in the magnitude of score differences) of tooth loss across dimensions. This does not seem the case.

R. Although we share the insights of the reviewer, we still think that it is important to disclose the individual dimensions of the OHIP. Indeed, most of the available studies on the matter show these data too, regardless of their position of the multi or single dimensionality of the instrument. However, all the associations were carried out using only the final score.

It is also not clear why the logistic regression (Poisson regression? in the results) was used. I think a simple description of OHIP-14 summary scores across various clinical and sociodemographic conditions would be informative enough and would suffice as validation in this population.
R. We decided to perform the logistic regression for a more in depth analysis of the data. We consider this information important to have a comprehensive view on which of the patient’s variables is more decisive on affecting quality of life.

**OHIP’s major strength is that it is globally used.** How different oral conditions affect individuals and what other factors shape this experience is still of considerable interest for the dental community. The present manuscript could provide some valuable information about the oral health of older Chileans, and whether this population is similar to other elderly populations if presented scores were comparable with the literature.

R. Even if our OHIP-14Sp is slightly different to those reported in the literature, we already stated that for the important associations presented here, we only considered the final OHIP-14Sp scores and not those in each dimension. That being said, we think that our data will be comparable at a reasonable extent to those derived from other populations.