Author's response to reviews

**Title:** Cross-cultural adaptation and psychometric properties of the Brazilian-Portuguese version of the VSP-A (Vecu et Sante Percue de l'Adolescent), a health-related quality of life (HRQoL) instrument for adolescents, in a healthy Brazilian population

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**Author's response to reviews:** see over
Dear Natalie Pafitis,

On behalf of the authors of the manuscript “CROSS-CULTURAL ADAPTATION OF THE BRAZILIAN-PORTUGUESE VERSION OF THE VSP-A (VÉCU ET SANTÉ PERÇUE DE L'ADOLESCENT), A HEALTH-RELATED QUALITY OF LIFE INSTRUMENT FOR ADOLESCENTS”, I would like to thanks the reviewers for their thoughtful comments. We have revised the manuscript to take care of their considerations. Following are answers and comments to each of the questions they raised. We hope we were able to meet your requirements. Please contact us if you need any further explanations.

Sincerely,

EDITOR QUERIES

1. The editors asked for the following three modifications in the abstract:

   (1) Include context information within the background section of your abstract, in addition to the aims of your study, and (2) Define VSP-A and HRQoL within your abstract.

We have included the required information, and now the background section of the abstract reads as follows:

   Health-related quality of life (HRQoL) assessment, encompassing the different facets of adolescents' lives, is increasingly considered an important health outcome to be used to identify population health needs and to provide targeted medical care. Although validated instruments are essential for accurately assessing HRQoL outcomes, there are few cross-culturally adapted tools for use in Brazil, and none designed exclusively for use among adolescents. The Vécu et Santé Perçue de l'Adolescent (VSP-A) is a generic, multidimensional self-reported instrument originally developed and validated in France that evaluates HRQoL of ill and healthy adolescents. The purpose of this study was to cross-culturally adapt and validate the Brazilian-Portuguese version of the VSP-A for use in healthy adolescents.

   (3) Clarify, within your manuscript, whether you received informed parental consent for your study. If not, please clarify the reasons as to why this is the case.

We did not receive informed parental consent. The adolescents were 14 years old or more, and were considered to be legally able to independently consent to participate in research evaluating their own quality of life. The Ethics Committee of Rio de Janeiro State University approved the study, with the condition that all participants signed an informed consent form.

This paragraph on the Methods Section now reads as follows:

   “The Ethics Committee of Rio de Janeiro State University approved the study, and all adolescents signed an informed consent form. Informed parental consent was not required since the adolescents, at least 14 years old, were considered to be legally..."
able to independently consent to participate in research evaluating their own quality of life.

REVIEWER’S QUERIES

2. Reviewer 1 asked for the following:

(1) Title - Given that this validation study was performed in a strictly healthy population, this needs to be more explicitly stated in the title.

We acknowledge this observation and changed the title as follows:

Cross-cultural adaptation and psychometric properties of the Brazilian-Portuguese version of the VSP-A (Vécu et Santé Perçue de l'Adolescent), a health-related quality of life (HRQoL) instrument for adolescents, in a healthy Brazilian population

(2) Introduction - Please address in the Introduction whether there are other HRQOL measures that have been validated for Brazilian adolescents. It is mentioned in the Discussion section that the PedsQL and CHQ have been validated for Brazilian adolescents. In the Introduction section, the advantages of the Brazilian-Portuguese version of the VSP-A over these other measures needs to be addressed.

We added the following paragraph in the “Background Section”:

Few instruments evaluating teens’ HRQoL have been validated for use in the Brazilian socio-cultural context. Two instruments are specific HRQL instruments. The Child Perceptions Questionnaire (CPQ11–14) measures the impact of oral health abnormalities on the quality of life of children (16,17), whereas the Childhood Health Assessment Questionnaire (CHAQ) assessing functional ability in daily living activities initially was developed to be used in children and adolescents with juvenile idiopathic arthritis but also applied in other disabling conditions (38, 22). Two others are generic HRQL instruments. The Child Health Questionnaire (CHQ) (mcs38, mcs39) was modeled after the SF-36 constructed to survey health status in the Medical Outcomes Study. The Pediatric Quality of Life Inventory (PedsQL) (18,19,20) was derived from the Pediatric Cancer Quality of Life Inventory (PCQL), and its items were created based on the existing literature, interviews with patients and their families, and discussions with healthcare professionals. When our study was implemented, the parent form of the CHQ (CHQ-PF50) was the only generic tool validated in Brazilian. Since it was neither developed according to the teen’s point of view nor self-reported by the adolescents, we were not prone to include it in our study.

(3) Reviewer: Also, while the benefits of self-report are emphasized in the Introduction, there are also times when parent proxy-report will be important given that parents’ perceptions of their adolescents often drive healthcare utilization and some adolescents may be unable to self-report due to cognitive deficits. Please discuss this.

The use of a parent-proxy version of the VSP-A is addressed in the Discussion Section as follows:

“Besides, although the benefits of collecting adolescent’s self-reports of HRQoL are widely stressed, the fundamental role for parent proxy-reports in clinical trials and health services research should be mentioned. In situations where the adolescent is unable to complete a HRQoL tool, such as in cognitive deficiencies or severe diseases, HRQoL assessment should rely on proxy reports or else be given up. Furthermore,
given that perceptions of the parents or guardians often drive health care utilization, parent proxy-reports may be useful to better understand factors impacting the access to healthcare dedicated to children and adolescents. Parent-proxy reports can provide complementary information regarding adolescents’ mental health and well-being (48, 49). Therefore further studies are necessary to evaluate the applicability and validity of the parent-proxy version of the VSP-A in the Brazilian context (mcsJAH 2001).

(4) Methods: Please clarify whether parents, teens, or both signed informed consent forms.

We clarified, in the Methods Section, that the adolescents signed informed consent forms. This paragraph on the Section Methods now reads as follows:

“The Ethics Committee of Rio de Janeiro State University approved the study, and all adolescents signed an informed consent form. Informed parental consent was not required since the adolescents, at least 14 years old, were considered to be legally able to independently consent to participate in research evaluating their own quality of life.”

(5) Since students were asked if they would agree to be interviewed again at about 2 weeks, do you believe there is some potential for bias in the test-retest data? This needs to be addressed.

The following paragraph was added in the Discussion section:

With regard to the reproducibility testing, the test-retest method with students agreed to be interviewed twice may have led to several bias. One the one hand, there is a potential for learning, carry-over, or recall effects. A very short time interval makes the carryover effects due to memory, practice, or mood more likely, whereas a longer interval increases the chances that a change in status could occur. The two-week time interval chosen in our study is generally believed to be a reasonable compromise between recollection bias and unwanted (on the part of the investigator) change in health condition [Marx JCE 2003]. To reduce the potential change in health condition, the adolescents were asked whether major life events leading to either hospitalization or absenteeism occurred in the given time period. On the other hand, although less than half of the whole sample was involved in the retest the existence of a selection bias is not likely since no difference was found between adolescents included in the retest and those who were not with regard to major features. Overall, the potential for bias in the test-retest data remains limited.


(6) More information is needed about the pilot testing of this measure. For example, what procedures were used, what were the results, what were the demographics of the 14 adolescents? It might be useful for the authors to include a separate appendix where a greater level of detail about the pilot testing and translation process is included.

Details on the translation process and on the pilot test were added and the paragraph now reads as follows:
Brazilian translation and conceptual equivalence. A forward-backward translation was performed. The French version was translated into Brazilian-Portuguese by a Brazilian-Portuguese native speaker with a high level of fluency in Portuguese and French. The back-translation into French was undertaken independently of the forward-translation by a French native speaker. A panel of pediatricians and researchers experienced in the cross-cultural adaptation of instruments, fluent in French, discussed the divergences observed between the back-translation and the original French version in order to identify the difficulties emerged from the translation process. These difficulties were discussed with the authors of the original instrument and the items were reworded where agreement could not be reached. Then, a provisional VSP-A version was established and pilot-tested in a public high school in the municipality of São Gonçalo, in a sample of 14 adolescents (age range 14-16 years, 64.2% girls) that were not included in the validation study sample. All the students in the pilot test signed an informed consent form. They were asked whether the items were clear and understandable, and to rate the level of difficulty and relevance of each item. They were also asked to make suggestions in order to modify items they found difficult or irrelevant. At the end of the questionnaire there was an open question asking the respondents to report their opinions, suggestions or comments on the instrument. The adolescents all agreed that the Brazilian-Portuguese version of the VSP-A was clear, that the language was of common use, that the items were relevant and the instrument was in a comprehensive format. The results of the pilot-test were peer-reviewed yielding a final version of the Brazilian-Portuguese VSP-A conceptually equivalent to the French original VSPA and linguistically appropriate for use among Brazilian adolescents. This final version of the Brazilian-Portuguese VSP-A was implemented in a validation field study conducted among a large sample of students (Figure 1).
Figure 1 summarizes the procedure including the forward backward translation and the pilot test. We let the Editor decide whether it is necessary to include it in the manuscript.
(7) Why did the authors not examine the chi-square statistic?
At the end of the Method section, the statistical tests used in the analyses were presented (see copy of this paragraph below), and indeed we used Chi square tests when they were applicable (it was also indicated in the footnote below the table 1) “Description of the population features. Standard descriptive statistics of the sample characteristics were computed: means and standard deviations for continuous variables, and effectives and percentages for categorical variables. Groups of adolescents were compared using Chi² tests or accurate Fisher tests for qualitative variables, and ANOVA or Mann-Whitney tests for quantitative variables depending on the conditions of application. For all tests, statistical significance was set at p < 0.05.”

(8) How was whether an adolescent had a major life event occur in the 2 week test-retest time frame assessed? If adolescents reported on this, do you think there is a possibility that adolescents would underreport the occurrence of a major life event? How might this impact the findings?

The adolescents were asked if they have had a major life event in the interval between test and retest, that is, disorders that led to absenteeism or hospitalization. Even if they may have underreported these events, we think that if such events actually occurred there would be no reason for denying, even more since the confidentiality of the answers was ensured and they would not expect anything from not reporting such events. Apart from this, we have no strong argument to discuss this point.

(9) Results: Please put the p-values in the text of the manuscript.

We checked that all p-values were mentioned in the text of the manuscript.

(10) Please clarify how the mean completion time was computed.

We acknowledge this observation and this issue was addressed in the Methods section, as follows:

The mean time needed to complete the VSP-A Brazilian-Portuguese version was also calculated as the difference between start time, namely the time the questionnaire was given to the students, and the end time, when they returned the instrument fulfilled. A short time of completion suggests a greater acceptability for both “users” and respondents.

3. Reviewer 3 asked for the following:

(1) One minor aspect however would be to compare VSP-A to other quality of life instruments available in Portuguese and Brazil.

We acknowledge this observation and we addressed this issue in the both in the introduction and in the discussion sections.

See response #2 to reviewer1 and discussion section, as follows:

More recently, the PedsQL was adapted and tested with Brazilian adolescents and their parents [40, 41]. The comparison of these different HRQoL questionnaires in a large sample of Brazilian-Portuguese adolescents would bring useful information for the users of HRQoL helping in the choice of the questionnaires the most suitable to the study purpose.
4. Reviewer 2 asked for the following:

(1) According to authors, the original instrument aims to assess both healthy and ill adolescents’ HRQoL. In the present study, only adolescents attending school were recruited. In addition, the recruitment had a higher chance to include the most healthy subjects (as acknowledged by authors). It would be interesting to recruit ill adolescents (maybe in an outpatient clinic for adolescents) to test whether the instrument is also suitable for this subpopulation. Why did authors decide not to recruit these subjects? It should be also commented in the discussion section.

We acknowledge this observation and we clarify that the objective of this study was to have a baseline evaluation of the adolescents’ HRQoL. We addressed this issue in the Discussion Section, as follows:

Furthermore, the current data support the application of the Brazilian-Portuguese version of the VSP-A in healthy adolescents, in school settings. Further evaluation of the instrument is needed, including analyses of item performance and scale validity among adolescents with various diseases or health conditions.

(2) Overall score: Authors informed that the instrument generates 10 scores (one for each subscale) and an overall score. Even though the overall score might show a good psychometric performance, the clinical meaning of a single score that summarizes 10 distinct domains is debatable. Authors could discuss this issue too, in order to provide readers with a theoretical position.

This issue is addressed in the Methods Section as follows; A score for each dimension scale was calculated as well as a total index (VSP-A index), derived by summing the scales, that can be interpreted as a global rating of the overall adolescent’s HRQoL.

(3) Results showed a high rate of missing values for sexuality/sentimental in the Brazilian sample. What were the missing values in France? Are they comparable? If so, is this item sufficiently able to assess sexuality? Which alterations could be done to improve the performance of this item?

This issue was already addressed in the Discussion section (see copy of the paragraph below):

“Apart from the dimension of sentimental and sexual life, the low level of missing data confirmed the instrument acceptability. The pupils were oriented to skip any item they chose not to answer. Possibly, some did not feel comfortable answering both items about sexual and sentimental life, but the score of this dimension was considered as missing when at least one item was not answered. Nevertheless, answering only one of the items would remain meaningful. The same degree of missing scores for this scale was observed in the French sample. There was no gender difference in the completion rate of those items. To avoid this issue, the scoring method could be reviewed so that score could be computed as for the other dimensions when at least half of the items are answered, and thus as soon as one of the items of the sentimental and sexual life dimension is answered.”

(4) How to explain that 88.8% of the sample had at least one psychosomatic symptom per week (in a community sample, theoretically more healthy than the general population)?

We addressed this issue in the Discussion Section as follows:
At last, the high frequency of psychosomatic symptoms reported by the students (88.8% of the sample with at least one symptom) could be surprising. Nevertheless, the symptoms assessed in the Psychosomatic Symptom Checklist represent very common complaints, such as headache, backaches, insomnia, fatigue, weakness, constipation, diarrhea, eye pain associated with reading, nausea and stomach pain. As the adolescents were in a particular moment of their lives, because they were finishing the high school and preparing to enter a college or job market, they could present a variety of symptoms. One explanation could be that the exams required to enter a college influence the somatization in this community sample.

(5) Authors used Rasch analysis to assess individual item fit. In fact, Rasch Analysis is a very powerful tool to assess individual fit, as well as unidimensionality and DIF. What reasons based authors’ decision to use Zumbo’s ordinal logistic regression analysis, and not Rasch analysis? What advantages the former has when compared to the latter?

The following explanation was added in the Discussion section:

“Zumbo’s method using ordinal logistic regression (OLR) was favoured since OLR-based techniques were found to be superior to Mantel-Haenszel in identifying items that had nonuniform DIF (Crane Med Care 2006)”.


(6) The results showed that item 28 had extensive problems. Also, 11% of the items showed DIF problems. Specifically, the items with DIF may impair the comparability of the assessments by the original and the brazilian versions of the instrument, since subjects with the same trait have different probabilities of endorsing these items. What suggestions authors have to deal with this limitation?

Regarding item functioning across cultures, most VSP-A items appeared to function equivalently across France and Brazil. Four of 36 items showed significant DIF (11%), but the effect sizes for the DIF was small for all the items except for two of them (28 “good physical shape” and 34 “confidence in yourself”) [29]. Since it is the first psychometric analysis of the Brazilian VSPA, these results should be verified when the scale will be used in distinct samples. The translation of these items should also be verified. Nevertheless, when DIF is detected for an item, several methods have been proposed for correcting for DIF: one of them is based on the calibration of item parameters using IRT analysis in order to allow the calculation of person Rasch scores adjusted for DIF (Crane P JCE 2006). At last, items exhibiting DIF would be candidate for deletion when a shorter version of the questionnaire will be elaborated.