Author's response to reviews

Title: The World Health Organization Quality of Life Instrument for People with Intellectual and Physical Disabilities (WHOQOL-Dis): evidence of validity of the Brazilian version.

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Author's response to reviews:

COVER LETTER


Response to reviews received from Dr. Heloisa Di Nubila and Dr. Katayoun Rabiei.

Dear Dr. Anna Peeters
BioMed Central Editorial

The purpose of this communication is to list the changes performed in the manuscript #1093019121103075 in response to requests on the two received reviews. To facilitate monitoring we copied below the comments made by the reviewers and then subsequently described the action taken. We sincerely appreciate the attention to qualifying this manuscript.

We would like you to know we have submitted the article to a review with a native speaker who currently lives in Brazil. So, we do hope it is ok in what refers to language now.

We are at your disposal to provide further information.

Sincerely, Juliana Bredemeier

Reviewer's report

Title: The World Health Organization Quality of Life Instrument for People with Intellectual and Physical Disabilities (WHOQOL-Dis): evidence of validity of the
Brazilian version.
Version: 2 Date: 14 November 2013
Reviewer: Heloisa Di Nubila

Reviewer’s report:
Minor Essential Revisions: Page 6 -10th line – “As the concept of disability has not yet been widely disseminated in Brazil,...” – Discussion: This phrase is not clear and not correct, because the words and concept used in the study are not as the commonly used in Brazil: Categories intelectual; physical (meaning motorimpairments, amputations, plegias); visual; hearing and multiple. This could bebriefly explained.

Change(s) performed –The following text has been inserted: “According to the ICF, disability is the opposite of functionality, both of which being the result of changes in the body and its consequence in the activities and participation of people. Thus, problems relating to activity limitation or participation restriction are described as disabilities. On the other hand, non-problematic aspects of health and states related to it are defined under the term functionality. In other words, disability is used to "to denote a multidimensional phenomenon resulting from the interaction between people and their physical and social environment" [1]. Impairments are defined as “problems in body function or structure as a significant deviation or loss" [1]. In Brazil, where the term disability is considered pejorative (such as if it referred to a lack of ability), there was a movement to instill a preference for the expression person with special needs to designate those people with an injury or disability. Historically, the term impairment has been used interchangeably with this expression within this country. However, neither the term impairment nor the expression person with special needs fill in the gap between the presence of an injury or disease and the occurrence of a loss of functionality. Neither one of the previous seem to take into account the fact that “two persons with the same disease can have different levels of functioning, and two persons with the same level of functioning do not necessarily have the same health condition" [1]. The matter of the term disability not being one widely spread in Brazil had an impact on data collection which we explain further”.

Another thing I would suggest to explain, would be the severity of conditions of visual and hearing problems in the persons selected for answering PD forms, how the group dealt with blind and deaf respondents.

Change(s) performed –The following text has been inserted: “Because it was usually not possible to know in advance the kind of PD the participant had, such that we could not be prepared in advance, people with hearing impairment had to be able to read Brazilian Portuguese and people with visual impairment had to be willing to have the instruments read by the administrator. In the end of the administration there was a space for the participant to register comments,
suggestions, and difficulties on the completion of questionnaires”. As to disability severity, it was evaluated only through the participant’s perception on his/her disability status. This information was taken into account in the analysis.

Level of interest: An article of outstanding merit and interest in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:
'I declare that I have no competing interests'

Reviewer’s report
Title: The World Health Organization Quality of Life Instrument for People with Intellectual and Physical Disabilities (WHOQOL-Dis): evidence of validity of the Brazilian version.
Version: 2 Date: 29 December 2013
Reviewer: Katayoun Rabiei

Reviewer’s report:
I) Major Compulsory Revisions
Background:
1- Page 6: “Inclusion and exclusion criteria” should be moved to the Methods section.
Change(s) performed – The topic has been removed to the Methods section.

2- Page 6: Why did you select only the institutionalized patients? Was there any logic behind it or did you only intend to simplify sampling?
Change(s) performed – The expression “Because of sampling convenience” was introduced in the text were we mention the participant’s origin: “Because of sampling convenience, all participants were required to attend (or be institutionalized at a facility specializing in the care of persons with disability, non-governmental organization, school, or health care facility”.

3- Page 6 line 13: In this part you have to define disability (both physical and intellectual disability) with references.
Change(s) performed – The following text has been inserted: “According to the ICF, disability is the opposite of functionality, both of which being the result of changes in the body and its consequence in the activities and participation of people. Thus, problems relating to activity limitation or participation restriction are described as disabilities. On the other hand, non-problematic aspects of health and states related to it are defined under the term functionality. In other words,
disability is used to "to denote a multidimensional phenomenon resulting from the interaction between people and their physical and social environment" [1]. Impairments are defined as “problems in body function or structure as a significant deviation or loss” [1].

4- Page 6 line 16: How did you do this screening step? By which questionnaire? What do you mean assertive manner? How did you recognize this assertive manner?

Answer– Because of the length of the article, it was our choice not to go any deeper on the instruments used for screening. The “assertive manner” refers to the capability of the participant not fail on the competences evaluated by both screening tests. The tests used for screening are mentioned in the text in the article (“Two instruments were used for screening: Test of Acquiescence (adapted from Cummins [14]), designed to determine whether the subject merely tends to agree with the interviewer’s questions (acquiescent responding) or is capable of providing actual answers even to reverse-scored questions; and the Test for Discriminative Competence (adapted from Dalton and McVilly [15]), which seeks to ascertain whether the participant is able to discriminate his or her chosen response on a three-point scale. Participants with ID were excluded from the sample after failure in both screening tests”). It is our suggestion that no changes are performed within this topic.

5- Page 6 line 17: How and why did you categorize ID persons? What is the reference for categorization?

Answer – ID participants were not categorized. A question was made as to access their perception on the visibility of disability, variable that was later included in the analysis. Intellectually disabled participants were included only when cared for at a service dealing specifically with the care of persons with ID.

6- Page 6 line 17: Were these two tests performed on Mild ID persons who were screened in the last step? Or did you use the screening for mild ID subjects?

Answer – Because ID participants were not categorized, the screening test was used with all ID participants prior to entry in study.

Methods: The methods section should be rearranged because the process of your study is incomprehensible and unordered. Many important things were not mentioned in the manuscript. Please clarify:

1- What was your study design?
2- What was the area of the study?
3- How did you find your target group?
4- What was the sample size?
5- What was the sampling method? Did you have a randomized sampling method?
6- Who evaluated the disabilities?

Change(s) performed – The following text has been added to the Methods section: “The sample was drawn by convenience. The WHOQOL Group establishes a number of participants per centre based on extensive experience in studies of this nature. Because this is a cross-cultural, simultaneous and original study, it is difficult to rely on literature or sample calculations. Thus, it was stipulated the goal of 150 people with physical disabilities and 150 people with intellectual disabilities for each participating centre”. As to disabilities evaluation, they were personally evaluated in the case of PD (see flowchart) and established through the participant’s attendance to an ID centre in the case of IDs.

7- Page 7 line 8: I can't understand. Did you use the WHOQOL-Dis and compare it with other topics from a qualitative study? If yes, please cite the reference. If there is not any published data, you have to describe the qualitative study.

Answer – The article that presents all data from the cross-cultural development of the DISQOL measure is mentioned in the study [13]. It is an understanding of the WHOQOL Group that, in case of cultural differences, new items may be generated in this new culture. We had reason to believe, based on the analysis of the focus groups that this might be the case in Brazil. The results of the tests performed to check this assumption are in the present article.

8- Page 8 WHODAS II: This questionnaire measures disability. Did you use it for the screening or in the main study? Did you validate this questionnaire in this study? Did you use only Cronbach’s alpha to validate it? If you had validated it before this study, please mention the reference.

Answer – The WHODAS-II was used in the main study and its results have been used for validation of WHOQOL-Dis. The questionnaire has been translated into Brazilian Portuguese by our group following all current recommendation for translation and validation of questionnaires. The validation study has yet not been finished. This is a publication in process. This is why we refer to the international publication to provide Cronbach alpha of the instrument, and not on a local publication.

9- Page 9: You used two other questionnaires (satisfactory and Beck) in this study for convergent validity. You had to validate these two questionnaires before this study. Did you do it? I checked your references. Reference 20 is a paper about the main questionnaire and number 23 is a Portuguese paper which I could not check. In general, why did you choose only these two questionnaires?

Answer – The “Satisfaction with Life Questionnaire” was developed by [20] and translated and validated by [21]. However, because no information on Cronbach alpha is available on publication [21], we inserted only the original Cronbach alpha. “Beck Depression Inventory - II” was developed by [22] and translated in Portuguese by [23]. As the Cronbach alpha for the local version was available, we decided to offer the local information. Both have been included due to
previous studies. In the case of Beck, many studies have related the existence of an inverse relation between QOL and depression. The “Satisfaction of Life Scale” is thought to have a positive relation with QOL. Therefore, it was the recommendation of the Coordination Centre to include both instruments in the data collection.

10- Page 9 line 11: What do you mean “logistical reasons”? Please clarify your reasons.

Change(s) performed – The information “For convenience reasons” was inserted in the text.

11- Page 10: Did only you use two questions for measuring the construct validity?


Discussion:
As you showed in your results, the new components extracted from factor analysis were different from the three factors of the DISQOL module. Now what is your suggestion?

Answer – We tried to state our suggestion when we say the ideal choice is to use the cross-cultural model: “Hence, we understand that the use of the Brazilian Portuguese versions of this instrument – which have been validated by this investigation – with the underlying factor structure generated during the original cross-cultural project will not be deleterious in any way”.

II) Minor Essential Revisions
Abstract:
The abstract should be shortened.
Result: It seems that this part is a conclusion and not the results.

Change(s) performed – We rephrased the Results section of the abstract. Because of that, we are afraid we did not manage to shorten the abstract as much as expected.

Background:
1- Page 4 line 12: I think this frequency (nearly 22% of the population with disabilities) is too high. It is better to define disability first.
Change(s) performed – The following text has been inserted: “Even though this percentage may be overestimated due to possible problems in the Census data collection, the number of people with disabilities is growing as population is shifting toward an inverted age structure” (…).

2- Page 5 line 1: The reference number should be moved to the end of phrase

Change(s) performed – The reference number has been moved as oriented.

3- Page 5 line 9: You did not define quality of life. In your explanation in this line it seems that quality of life is only an instrument to evaluate the psychological and medical status.

Change(s) performed – The following text has been inserted: “There are many definitions in literature for QoL, with the one published by the WHO in 1995 being on the most accepted. According to the WHO, QoL refers to “an individual's perception of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations, standards, and concerns [7]”.

Methods:

1- Page 7 line 9: Who were these three judges?

Change(s) performed – The following text has been inserted: Experienced in the matter of disabilities.

2- Page 7 line 10: Do you mean you had translated the items extracted from your qualitative study into English?

Answer – Yes. The whole process is explained in Reference 13. After the cross-cultural version was proposed (in English) we also confronted the items with the material emerged within the focus groups discussions.

3- Page 7 line 13: who were the two experts and how did you select them?

Answer – They were the same judges previously mentioned. Change performed: we substituted the word “experts” by “judges”.

4- Page 7 line 14: In general, did you extract the new concepts from FGD and add them in the original questionnaire?

Answer – We are very sorry, but we didn’t understand what FGD mean.

5- Page 7 paragraph 3: You have to move this paragraph after the explanation of WHO pilot study in line 7.

Change(s) performed – The requested change has been performed.

6- Page 8 line 12: “participants’ perceptions of their health status and disability” is not a demographic characteristic.
Change(s) performed – The text has been replaced by “About you’ questionnaire: designed to collect sociodemographic data and assess participants’ perceptions of their health status and disability”.

7- Page 8 line: The module has 12 items both in the WHO paper that you cited and in table 1 of your manuscript.

Answer – There are 3 F1 items, 3 F2 items, 6 F3 items and 1 Overall item = 13 items (See Table 1).

8- Page 9: At the end of this page you wrote” This protocol was the subject of extensive discussions between the investigators and the Hospital de Clínicas de Porto Alegre Research Ethics Committee”. So, what decision did you finally make?

Answer – There is a sentence before the one mentioned in this comment that explains our decisions. We copy it here: “Protocol interventions ranged from notifying the participant of the need for in-depth assessment for depression to notification of the care team in participants positive for suicidal ideation”.

9- Page 10 line 19: What were the independent samples?

Answer – PD and ID. As written in the text, “All analyses were based on classical psychometric methods and were conducted independently for the two study samples (PD and ID)”.

10- How did you complete the questionnaires? Were there any differences between self- and interviewer-administered questionnaires?

Answer – Differences in questionnaire administration were not computed in the analysis.

Results:

1- Page 11 line 21: I think the question “Are you satisfied with how your environment is adapted to your limitation?” is an item for PD subjects not ID subjects.

Answer – we kindly have to disagree. According to WHO’s ICF, “environment” is taken as something broader than geography: “Environmental factors make up the physical, social and attitudinal environment in which people live and conduct their lives” (p.10) [1].

2- Please write the important results from tables 7 to 10.

Change(s) performed – The requested change has been performed.

Discussion:
1- Page 13 line 20: Do you mean perception to be healthy and not healthy?

Answer – Yes, as mentioned in item 2 of the Methods section.

2- Page 13 line 22: I cannot understand. you did not mean being healthy in the questionnaire and you only asked the perception of the subjects. So, why do you think the PD subjects did not positively answer this question after a mild illness?

Answer – The objective was to value the individual's perception, and not the clinical status. This is in accordance to the WHOQOL’s definition of QOL [7].

Conclusion:
1- Page 17 line 3: As you wrote in the methods, you have evaluated this questionnaire only for mild intellectually disabled subjects. Please remove the “moderate” intellectual impairment.

Change(s) performed – The requested change has been performed.

2- This study has not evaluated the validity and reliability of the questionnaire in a randomized sample group. Moreover, you found differences between your gathered factors (from factor analysis) and the three factors of DISQOL module. Meanwhile, you did not check test-retest reliability for physically disabled subjects. I think it is better to write a more cautious conclusion.

Change(s) performed – The requested change has been performed.

Tables and figure:
1- Figure 1: Are there any references for this figure or was it only your approach? If this was your approach, please clarify your reason about it in the methods section.

Change(s) performed – We think the answer given to the first comment of Dr. Di Nubila applies also here: “In Brazil, where the term disability is considered pejorative (such as if it referred to a lack of ability), there was a movement to instill a preference for the expression person with special needs to designate those people with an injury or disability. Historically, the term impairment has been used interchangeably with this expression within this country. However, neither the term impairment nor the expression person with special needs fill in the gap between the presence of an injury or disease and the occurrence of a loss of functionality. Neither one of the previous seem to take into account the fact that "two persons with the same disease can have different levels of functioning, and two persons with the same level of functioning do not necessarily have the same health condition" [1]. The matter of the term disability not being one widely spread in Brazil had an impact on data collection which we explain further”. (Please observe that the text just in between quotation marks has been inserted in the manuscript.)
2- Figure 1: The answer to the question “Does this illness limit or restrict your social interactions with others (activity participation)?” may be yes not only in patients with disability but also in individuals with depression or some other mood disorders.

Answer – This was one of the reasons why we had a measure of Depression (Beck II) included in study.

3- Tables 2 to 5: Please write the items of the module or explain the numbers of the items in table footnote.

Answer – We are very sorry if we did not understand this request. We have provided the number of the items as well as the factor in which they loaded in the original study in all tables. Considering this is a validation study, it is important to bear in mind that there we are not proposing a final organization to the items in Brazilian Portuguese. We found it to be more important to provide the reader with the steps we took in our analysis so that he/she understands the choices and recommendations we make.

4- Table 7: What do you mean “years of study”?

Answer – Our levels of study in Brazil differ to the ones in the USA and Europe. Therefore, it has been recurrent for Brazilian researchers to inform the years the person spent studying instead of saying “high school” or “some undergrad school”.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
'I declare that I have no competing interests