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A protocol for Italian validation of DEMQoL-Proxy Scale: assessing the Quality of Life of people with moderate or mild dementia.

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Abstract. In this paper, we propose an adaptation of a tool's validation protocol. We adopted this phases-theory to validate in Italian language an instrument to assess Quality of Life for people with moderate or mild dementia. We will explain the example of our Italian validation of DEMQoL-Proxy considering each De Vellis's phase. We will explain our application of De Vellis's model to Italian example described. For the first three phases, we reproduced the original validating study in which authors (Smith et al., 2005) defined what to measure, how to generate a set of items and the structure of the scale. Indeed, for the last five phases we explained the adaptation of De Vellis's model to Italian validation. We hope that this model could be effective for validating goals, for researchers and for all professionals who deal with caregivers and patients with moderate and mild dementia. Furthermore, the measurement of the Quality of Life makes the scale widely useful within the various professional specialties and settings. Finally, thanks to the methodological assumptions adopted following the De Vellis's eight-phase model, we can affirm that this first Italian pre-validation of the DEMQoL-Proxy appears to be an excellent forerunner for its effective validation within the Italian context.

Key words: Quality of Life, Dementia, Content Validity, Face Validity, Back-translation

Introduction

In this article we propose an adaptation of a tool's validation protocol. We have utilized a phases-theory to validate in Italian language an instrument to assess Quality of Life for people with moderate or mild dementia. We will explain the example of our Italian validation of DEMQoL-Proxy sound out each De Vellis's phases (1).

In this above-cited paper (1), author illustrates a procedure to develop a scale of measurement. The approach includes eight phases:

1. Determine what to measure
2. Generate a set of items
3. Determine the structure of the scale
4. Review of the items by a panel of experts
5. Consider the introduction of validation item
6. Submit items to a sample of subjects
7. Assess the reliability of the scale
8. Optimize the scale

The scale validation protocol

We will explain as we have considered De Vellis model (1) to our Italian example. For the first three phases, we have inherited the study on first original validation in which authors (2), have yet determinate

what to measure, how generate a set of items and the structure of the scale.

Indeed, for the last five phases we have explained as adapt the model of De Vellis (1) to our Italian language validation.

First Phase - Determine What to Measure

In this first phase, it is essential to determine the construct of interest to be measured. Over the past 15 years a considerable number of instruments have been introduced for assessing phenomena that are not observable or not directly measurable, such as Quality of Life (QoL). Given its complexity, there is growing consensus on the need to measure patient-rated broad outcomes such as QoL in different populations: the more complex is the patient's clinical condition, the more relevant will be his context for his perceptions, his beliefs, his emotions and his daily life experiences. And referring to the clinical situation, dementia is certainly one of the most common and complex diseases: it causes irreversible decline in global intellectual and physical functioning and has a significant impact on the patients, their family carers, and health and social services.

In the list of available instruments, we find out that two of them could be a valid solution in assessing broader outcomes in psychosocial experience for people with Dementia: DEMQoL and DEMQoL-Proxy (2), two standardized questionnaires designed to measure QoL of people with neurocognitive disorders in mild and moderate forms of dementia.

DEMQoL-Proxy is designed to be submitted to the caregiver, especially useful to overcome problems related to assessing the subjective perceptions and experiences of people lacking memory, attention, communication, judgement, insight and behaviour (3).

Second Phase - Generate a set of Items

DEMQoL-Proxy refers to a multidimensional model generated by exploration and measurement of behavioural and psychological symptoms that typically affect the well-being of the person, such as restlessness, depression, anxiety, disinhibition, and irritability.

In the original validation (2), the items were generated after collection and analysis of qualitative interviews on a sample of 19 patients and their caregivers.

These qualitative interviews were reviewed and discussed by a team of experts, including a focus group, with community psychiatric nurses working with people with dementia, and a carer's group of family carers.

The final-actual version contains 32 items and includes five domains: daily activities and looking after yourself; health and well-being; cognitive functioning; social relationships, and self-concept.

Third Phase - Determine the Structure of the Scale

In the primary paper on first validation authors (2), chose the Likert scale because in a pre-testing phase it seemed to be the most easily understood. Actually, the set of response options used in the final version of the questionnaire provided an intensity rating ('a lot/quite a bit/a little/not at all'), except in the thirty-second item in which it is asked only to indicate the level of quality of life (from very good to poor), and the answer is referred to the last week. Carers were asked to give the answer that they thought the person with dementia would give.

Referring the structure of the scale, items respond to three main concerns:

- The thoughts of an individual towards his own feelings (11 items), i.e "In the last week, would you say that _____ (your relative) has felt cheerful?"
- The thoughts of an individual toward his memories (9 items), i.e "In the last week, how worried would you say _____ (your relative) has been about forgetting things that happened a long time ago?"
- The thoughts of an individual about his daily life (11 items), i.e "In the last week, how worried would you say _____ (your relative) has been about keeping him/herself clean (i.e washing and bathing)?".

To assess psychometric properties, the scale was completed by 126 caregivers; after this first phase all items with poor psychometric performance and therefore with little scientific relevance were eliminated. In

addition, individual questions and answers have been evaluated and the results are two shorter, but richer forms of scientific content. In the second step, the new version was subjected to 99 caregivers, to prove its acceptability, reproducibility, and validity (4).

These two steps allowed the application of the questionnaire to a larger sample (225 caregivers) showing that DEMQoL-Proxy is comparable to the best tests in the field; it evaluates the QoL in people with mild to moderate dementia (Mini Mental State Examination > 10); it is promising for the Quality of Life assessment in severe dementias, but this would require further studies.

DEMQoL-Proxy could be potentially used in various care settings such as: specialist medicine departments, hospices, home long-stay settings in dedicated facilities (5).

Considering the validity of this questionnaire, it was considered appropriate to proceed with the validation study of the Italian version, reproducing all the necessary steps from the original study, for this purpose.

As we have introduced at the beginning of this article, we will now comment each phase of the model to try to adapt it for our Italian example. So, we detailed the protocol to validate Italian version of DEMQoL-Proxy.

Fourth Phase - Review of theIitems by a Panel of Experts: The Content and Face Validity

For a protocol validation of an instruments (1), content validity as referred to the grade of coherence between items and domains of interest of the scale. To consider it a valid scale, it must explore the construct and must cover the whole domain, being able to represent all aspects.

To verify content validity of DEMQoL-Proxy we have followed some steps. The first step was the back-translation of the DEMQoL-Proxy in Italian language. The translation was made by bilingual authors according to existing guidelines (6;7) and back-translations were made to guarantee the maximum adherence to the original version (2;8).

Written informed consent was obtained from subjects after a detailed explanation of the purpose of the study. We recruited Content Validity Panel of Experts and Face Validity Panel Group, both between January 2019 and February 2019. To test Content Validity, we enrolled a panel of 8 experts. We recruited two Medical Doctors, for each domain in which DEMQoL-Proxy can be used: two Medical Doctors working in the geriatric ward, two Medical Doctors working in the hospice, two Medical Doctors working in a residential structure, and two Medical Doctors working in home settings.

To enroll the panel of experts, to evaluate the Content Validity, we followed the methodology reported in the literature (9-11).

We prepared a questionnaire, specifically designed for the panel of experts. In this questionnaire, we asked to the experts to judge on Relevance and Exhaustively for each DEMQoL-Proxy item. Quantitatively, the experts were required to rate item on a 4-point Likert scale in terms of its relevance to the instruments aim using a specifically designed form: 1=not relevant, 2= relevant with item revision, 3= relevant with minor item revision, 4 = very relevant, experts give also a qualitatively suggestion. Then the medium of percentage score was the Content Validity Index (CVI). Content Validity Index consists in the medium percentage of experts' s answers. The acceptability cut-off of CVI is > 70% and in line with this cut-off we have considered any changing in the tool.

To explore Face Validity, we enrolled 6 participants: Three professional-care givers (Medical Doctor and Nurses) and three family caregivers. To assess Face Validity, we administered an ad hoc grid to the six experts to rate the 32 items of DEMQoL-Proxy on a two-level point scale (YES/NOT) about: difficulties, clarity, offensiveness. The answer of experts was considered on a qualitative way, to detect any request in line with a changing of the item. For any YES answer expert was required to give explanation. All participants recruited to test content and face validity, were able to perfectly read and understand Italian and to fill out the questionnaires by them-selves.

The DEMQoL-Proxy were administered to caregivers during their permanence in structures for visiting their relatives or working. The panel of experts assess if items are able to operationalize in a good way constructs ad sub-constructs and consequently eliminate no clear or irrelevant items. To

evaluate Content Validity of DEMQoL-Proxy, we have performed CVI-Content Validity Index (12), a 4-points Likert Scale which provides for .70 value as acceptability value. To test Face Validity, we considered answer in a qualitative way, just considered YES answer. In our validation results show that each item has a degree of agreement between experts of more than 70%. The Total CVI score is 0.90 (90% of agreement). In addition, it is noted that of the 32 items 12 obtained a total consensus from all experts. The detection of Content Validity through the administration of the Scale for the CVI provided an adequate degree of agreement between experts to proceed to the subsequent phases expected for pre-validation. Furthermore, the fact that most of the items in the questionnaire obtained a total consensus from all the experts represented a very important positive predictive factor. This results not required changing on the version of items proposed.

For the Face Validity also, 6 participants completed the *ad hoc* grid, but none of them gave YES answer. So, the qualitative results did not require any changing of the instrument. Our results point out that DEMQoL-Proxy seems to be understandable. In general, the items of the instrument seem to be clear, there is no difficulty in answering questions and there are no questions that are offensive or irritating. The evaluation of Face Validity confirm that tool was clear, easy to fill and without offensive word. Our results point out that psychometric properties of the Italian pilot version of the DEMQoL-Proxy as back-translation, Content Validity and Face Validity in Italian language was verified. This allows to consider the suggested Italian version as a valid methodological precursor for a future complete Italian validation of the instrument.

Fifth Phase -Consider the Introduction of Validation Item

Follow the theory of De Vellis (1), could be useful add some items to improve validity of the scale. Those eventually items are called "validation items". In the present Italian validation of DEMQoL-Proxy, we haven't needed to add new item, because tool appears already complete clear and easy to fill.

After those phases, could be interesting to explore Criterion Validity, considered as the grade how total scoring of a scale seems to associate with another tools or criterion or golden standard. In our protocol of validation of a scale for mild or moderate dementia, we haven't assessed criterion validity because original validation published by Smith et al. (2005) has commented already in their paper that DEMQoL-Proxy was able to assess just mild or moderate dementia /but not severe dementia) as the result of their comparison. In fact, they have compared DEMQoL-Proxy scoring with Mini Mental State Examination (MMSE). So, we integrated these findings in our starting point.

Sixth Phase-Submit Items to a Sample

At this sixth phase, we enrolled a convenience group, to test the following part of a validation protocol. In this phase we tested the Reliability measure, as Internal Consistency with Cronbach's alpha and Structural Validity measure, with factor analysis.

For the Italian Validation, we have enrolled 181participants, a number that is sufficient to sustain the expected factor analysis. We have calculated that to sustain a factor analysis of a tool with 32 items, the minimum of subject must be 160. This minimum number was product by a multiplication of 5 for the number of items of the instrument. Convenience sample was recruited also respecting the proxy version. So, people included were always caregivers or Medical Doctor of the patients.

Seventh Phase-Assess the Reliability of the Scale

According to the model considered (1), Factorial Analysis can be used to identify how many factors (latent variables able to define the construct) we can pull out. In the Italian validation of DEMQoL-Proxy we have confirmed the original multi-dimensional nature of the tool, as this is represented by different latent variables and we did not eliminate items, as each item related to at least a latent variable. In the Italian validation, we have collected 182 questionnaires (90 professional caregivers and 92 family members). We have explored results product by EFA (Exploratory Factor Analysis), the percentages of cumulative variance explained by our validation is 50,55 %. Thanks to the matrix of rotated components, we have detected 4 factors. In this way, we have produced a validation with result like the original English version.

When a scale will be validated, it was supposed that item's scale is connected between the construct in a strong way. Also, they must be connected also each-other. This aspect is called -internal consistency-. It is possible to test internal consistency with inter-correlation and with di Cronbach' s alpha. In this Italian validation, we have not re-tested inter-correlation between items. In fact, this was yet explored in the original validation-version.

In our protocol, we have tested just Cronbach' s alpha, to assess proportion of variance shared by items ascribable to the investigated construct. The values that can be assume are included between 0 end 1. Values near 0 show a low reliability grade between, indeed values near to 1 show a high grade of scale coherence. The Cronbach' s alpha had a score of 0,825 on 31 items. This score can be considered a particularly good result in term of Reliability (1).

Eighth Phase- Optimize the Scale

Our Italian validation shows a very good Internal Consistency We consider the Italian adaptation of DEMQoL-Proxy as a reliable scale. We did not eliminate items, because the Face Validity and Cronbach' s alpha value support the whole version.

Conclusions

We hope that this model of validation of a scale protocol can be of help to those who want to undertake this goal, in their research and to all professionals who deal with caregivers and patients with moderate and mild dementia. Furthermore, the measurement of the Quality of Life makes the scale widely used within the various professional specialties and setting.

Finally, we can affirm that this first Italian pre-validation of the DEMQoL-Proxy, following the De Vellis eight-phases model (1), seem to be an excellent forerunner for its effective validation in the Italian context.

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