Introduction

Dementia is a chronic and progressive condition defined as a public health priority. Dementia causes decline in cognitive, physical and social functions, disability and increasing dependence on help from others in those affected (1,2); the World Health Organization (WHO) estimates 47 million people worldwide affected by dementia and forecasts that by 2050 there will be 132 million (1). The consequences on the economic and organizational level are imaginable, dementia represents substantial human costs for the society, family and individuals (3,4).

Dementia is therefore a particularly relevant problem and represents the first cause of the lowering of the Quality of Life (QoL) among neurodegenerative diseases (5).

The univocal definition of QoL has never been fully realized, the concept of QoL has constantly evolved over time and it is represented by a lot of definitions (6,7). WHO defines the QoL as “individuals’ perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (8). QoL is therefore generally recognized as subjective and multidimensional and its definition

Italian validation of the DEMQOL-PROXY: Exploratory Factor Analysis, Convergent and Divergent Validity

Alessandra Miraglia Raineri1, Chiara Bonfigliuoli2, Massimo Guasconi2,3, Francesca Camaiani2, Giovanna Artioli2 and Leopoldo Sarli2

1 Department of Health Sciences, Psychology and Psychiatry Unit, University of Florence, Florence, Italy; 2 Department of Medicine and Surgery, University of Parma, Italy; 3 Azienda Unità sanitaria Locale di Piacenza, Piacenza, Italy

Abstract. Background and aim of the work. We present in this paper a complete Italian validation version. We show some psychometric properties of the Italian version of the DEMQOL-PROXY: Structural validity (by use Exploratory Factor Analysis), convergent validity and divergent validity in Italian language. Method. We enrolled a sample of 182 caregivers of people with mild to moderate Dementia. In particular, we collected 90 questionnaires of professional caregivers and 92 questionnaires of family caregivers. We used Exploratory Factor Analysis (Varimax rotation), to identify the saturation of items on the relevant factors. The internal consistency of the instrument was evaluated by using the Cronbach Alpha coefficient. Finally, referring to the Validity of convergent and Divergent validity, we used Spearman’s correlation coefficient by comparing the various instruments of the study. Results. Our result shows that the variance explained by 4 factors corresponds to almost 51% of the total variance. Factors extracted in our Italian version are: Cognition; Negative and Positive emotion; Daily activity and Membership. Conclusion. The Italian version of the DEMQOL-PROXY point out very good psychometric properties: factors extracted are similar to the original version and convergent and divergent validity show good proprieties. We consider this paper as a complete Italian Validation. (www.actabiomedica.it)

Key words: quality of life; dementia, exploratory factor analysis, convergent validity, divergent validity
overlaps with that of a broader state of health that includes perception of health, physical, mental, social and role functioning (7,9).

Maintaining a good QoL is a primary and realistic goal of dementia treatment, therefore tools that assess quality of life are needed to evaluate the effectiveness of the interventions implemented (7,9,10). In the international context many tools have been developed to assess the QoL in dementia, but to our knowledge there are only two instruments validate in Italian language (7,11). The QOL-AD scale is indicated for patients with Alzheimer’s disease (12) and the QUALID scale is indicated for people with severe or terminal dementia (13), at the moment there seems to be a lack of an instrument in Italian that evaluates the QoL in patients with mild and moderate dementia. In Italy, about 400,000 people are affected by dementia in varying degrees of severity (3) and a tool is needed that can assess the QoL even in patients with a mild or moderate degree of dementia.

The dementia Quality of Life scale (DEMQoL) (14) was developed to assess the QoL in patients with moderate and mild degree of dementia, there is also a PROXY version that assigns the assessment to caregivers, applicable in different contexts (hospital wards, hospices, home and long care settings) (7). DEMQoL has shown good psychometric properties of validity and reliability, also confirmed in the German, Spanish, Chinese and Japanese versions and a recent review recommends its use for future studies (14–19).

A first evaluation of the Italian version of the DEMQoL-PROXY scale was made, demonstrating good psychometric properties for the face and content validity (7;20). In this paper we present the final complete results obtained from the validation of the Italian version of the DEMQoL-PROXY scale (7;20).

**Aim**

No Italian version of DEMQOL-PROXY has been validated in Italian language thus far. In line with this gap, we present in this paper a complete Italian validation version. We show some psychometric properties of the Italian version of the DEMQOL-PROXY: Structural validity (by use Exploratory Factor Analysis), convergent validity and divergent validity in Italian language.

**Materials and methods**

This is an observational study of the cross-sectional, using the Italian version of the DEMQOL-Proxy obtained from the pilot pre-validation study (7). It was approved by Ethics Committee of the Santa Maria Nuova Hospital of Reggio Emilia (protocol no. 2018/0141634; approved on 19/12/2018) and took 10 months to complete, from April 2020 to February 2021.

**Measurement**

We explored psychometric properties such as reliability of the original model, reliability of the questionnaire, convergent and divergent validity.

Specifically, for validities, we used the following validated scales:

1. The Italian version of QOL-AD - Quality of Life Alzheimer’s Disease (12) to explore convergent validity.
2. The Italian version of the CBI - Caregiver Burden Inventory (21;22) to explore divergent validity.

The Quality of Life in Alzheimer’s Disease [QoL-AD] (12) is a short and easy to submit questionnaire, it is in fact one of the most used scales in research. It consists of 28 items (interrogative form): 13 for patients with Dementia and 15 for their caregivers; it can be submitted to subjects who have obtained a score at MMSE higher than 11. The cut-off for impairment in cognitive skills is 26 (scores between 0 and 30). Authors identified five domains: cognitive, physical, psychological, social-family and related to the activities of daily life. Submission takes 10-15 minutes and items are rated on a 4-point Likert scale ranging from 1 (poor) to 4 (excellent).

The second scale is the Italian version of the CBI - Caregiver Burden Inventory (22), focused on the caregiver’s “burden of the care”. The CBI actually measures the burden that changes in the cognition and behaviour of patients with psychiatric, geriatric and
oncological diseases have on their families, and the patient’s consequent need for care and assistance. The point of view of the caregiver’s experience is multidimensional, in fact it investigates 5 different types of burden: burden-time dependence, developmental, physical, social, and emotional burden. It includes 24 items rated on a 5-point Likert scale ranging from 0 (at all) to 4 (very).

Sample eligibility criteria

The study included caregivers (professional and family caregivers) of patients with mild or moderate Dementia (with 10 to 20 Mini Mental State Examination); a convenience sample was recruited excluding caregivers of people with severe dementia and we did not collect sensitive data, as the focus is on the analysis of evaluating scale submitted to caregivers. Written informed consent was obtained from subjects after a detailed explanation of the purpose of the study.

So, we submitted the DEMQOL-Proxy scale, together with the CBI and QoL-AD scales to a total sample of 182 caregivers of people with mild to moderate Dementia. This included the samples recruited in the previous two years of study (2019 and 2020). In particular, we collected 90 questionnaires of professional caregivers and 92 questionnaires of family caregivers.

Statistical Analysis

The statistical analysis was performed by using IBM SPSS Statistics Version 25. We used Exploratory Factor Analysis (Varimax rotation), to identify the saturation of items on the relevant factors.

The internal consistency of the instrument was evaluated by using the Cronbach Alpha coefficient. To assess Convergent Validity and Divergent Validity, we used Spearman’s correlation coefficient to match the various instruments of the study.

Ethical considerations

The study has been conducted in agreement with the Ethical Principles for Medical Research Involving Human Subjects—the Declaration of Helsinki and it has been approved by the International Research Board of the University of Parma.

All the Hospitals where the study took place were contacted and were asked for their availability to participate in the research. An explanatory document of the study was sent to the coordinators of the operating units in order to inform them, and to agree on the access times in the structures.

All eligible participants were informed of the purpose and characteristics of the study and received a clear informative written document, explaining the design, aims, procedure and ethical considerations of the research. Informed consent was obtained before the professionals’ participation. Those who signed the consent have been informed that participation in the study was voluntary and that they could withdraw their consent to participate at any time.

Results

EFA and Construct Validity

Factorial analysis is performed to identify and describe relationships in a set of variables, allowing one or more factors or dimensions to be identified. The basic hypothesis is that the correlation between the variables is determined by unobservable dimensions (factors) that somehow determine the scores observed in the variables.

Table 1 shows that the variance explained by 4 factors corresponds to almost 51% of the total variance, an adequate percentage to the purpose of the analysis. It also emerges that the first factor accounts for 17% of variance, the second for 16%, the third for 12% and the fourth for the remaining part.

Then, Table 2 shows the rotated component matrix (Varimax), in which it is highlighted the major saturations for each item of the questionnaire, respectively to each of the 4 identified factors. We can note that for each factor there are at least 4 high saturations (adequacy criterion for the number of factors identified by the EFA). Table 2 presents the result of factor analysis: the Italian translation of the DEMQol-Proxy showed a similar structure of the original version. Questions #1, #2, #3, #4, #5, #6, #7, #8, #9, #10 load on a factor
namely Negative And Positive Emotion; questions #12, #13, #14, #15, #16, #17, #18, #19 and #20 load on the same factor of the original version Cognition; questions #21, #22, #27, #28, #29, #30 and #31 load on a factor that can be called Membership; questions #11, #23, #24, #25 and #26, load on the same factor namely Daily Activity.

Cronbach’s Alpha Coefficient

To verify the reliability of items included in the Italian version of the DEMQoL-Proxy scale, we used the analysis for the Cronbach Alpha coefficient.

In order to be acceptable, Cronbach’s Alpha is ex-

| Component | Initial Eigenvalues | Extraction Sums of Squares Loading | Rotation Sums of Squares Loading |
|-----------|---------------------|------------------------------------|---------------------------------|
| Total     | % of Variance       | % Cumulative                       | % of Variance                   | % Cumulative |
| 1         | 5.495               | 17.172                             | 5.495                           | 17.172       |
| 2         | 5.174               | 16.168                             | 5.174                           | 16.168       |
| 3         | 3.984               | 12.449                             | 3.984                           | 12.449       |
| 4         | 1.522               | 4.757                              | 1.522                           | 4.757        |
| 5         | 1.457               | 4.552                              | 1.457                           | 4.552        |
| 6         | 1.207               | 3.771                              | 1.207                           | 3.771        |
| 7         | 1.132               | 3.538                              | 1.132                           | 3.538        |
| 8         | 0.976               | 3.050                              | 0.976                           | 3.050        |
| 9         | 0.888               | 2.774                              | 0.888                           | 2.774        |
| 10        | 0.846               | 2.642                              | 0.846                           | 2.642        |
| 11        | 0.765               | 2.390                              | 0.765                           | 2.390        |
| 12        | 0.733               | 2.291                              | 0.733                           | 2.291        |
| 13        | 0.701               | 2.190                              | 0.701                           | 2.190        |
| 14        | 0.656               | 2.049                              | 0.656                           | 2.049        |
| 15        | 0.629               | 1.965                              | 0.629                           | 1.965        |
| 16        | 0.581               | 1.815                              | 0.581                           | 1.815        |
| 17        | 0.533               | 1.664                              | 0.533                           | 1.664        |
| 18        | 0.493               | 1.542                              | 0.493                           | 1.542        |
| 19        | 0.479               | 1.498                              | 0.479                           | 1.498        |
| 20        | 0.449               | 1.403                              | 0.449                           | 1.403        |
| 21        | 0.440               | 1.376                              | 0.440                           | 1.376        |
| 22        | 0.409               | 1.277                              | 0.409                           | 1.277        |
| 23        | 0.362               | 1.133                              | 0.362                           | 1.133        |
| 24        | 0.349               | 1.090                              | 0.349                           | 1.090        |
| 25        | 0.332               | 1.038                              | 0.332                           | 1.038        |
| 26        | 0.279               | 0.871                              | 0.279                           | 0.871        |
| 27        | 0.244               | 0.762                              | 0.244                           | 0.762        |
| 28        | 0.213               | 0.665                              | 0.213                           | 0.665        |
| 29        | 0.194               | 0.607                              | 0.194                           | 0.607        |
| 30        | 0.180               | 0.564                              | 0.180                           | 0.564        |
| 31        | 0.163               | 0.509                              | 0.163                           | 0.509        |
Table 2. Rotated component matrix

Rotated component matrix

| Component   | 1     | 2     | 3     | 4     |
|-------------|-------|-------|-------|-------|
| Cheerful    | 0.721 | -0.038| -0.182| -0.054|
| Worried or Anxious | 0.518 | -0.018| 0.195 | 0.303 |
| Frustrated  | 0.698 | 0.150 | 0.046 | 0.164 |
| Full of Energy | 0.568 | -0.012| 0.063 | -0.361|
| Sad         | 0.809 | -0.038| 0.062 | 0.021 |
| Content     | 0.681 | 0.018 | -0.074| 0.016 |
| Distressed  | 0.647 | 0.131 | 0.031 | -0.064|
| Lively      | 0.634 | -0.033| -0.041| -0.197|
| Irritable   | 0.595 | 0.161 | -0.165| 0.199 |
| Fed-up      | 0.697 | -0.048| 0.177 | 0.140 |
| That he/she has things to look forward to | 0.378 | 0.061 | -0.125| -0.460|
| His/her memory in general | -0.085 | 0.398 | 0.308 | 0.240 |
| Forgetting things that happened a long time ago | 0.001 | 0.617 | -0.169| 0.273 |
| Forgetting things that happened recently | -0.007 | 0.723 | 0.003 | 0.207 |
| Forgetting people's names | -0.028 | 0.785 | 0.051 | 0.036 |
| Forgetting where he/she is | 0.073 | 0.691 | -0.085| -0.165|
| Forgetting what day is it | 0.036 | 0.842 | -0.088| 0.067 |
| His/her thoughts being muddled | 0.142 | 0.755 | 0.173 | -0.022|
| Difficulty making decisions | 0.065 | 0.722 | 0.044 | -0.064|
| Making him/herself understood | 0.112 | 0.564 | 0.054 | -0.194|
| Keeping him/herself clean | -0.107 | 0.040 | 0.490 | 0.417 |
| Keeping him/herself looking nice | -0.203 | 0.007 | 0.584 | 0.412 |
| Getting what he/she wants from the shops | -0.003 | 0.018 | 0.390 | 0.714 |
| Using money to pay for things | 0.145 | 0.031 | 0.219 | 0.809 |
| Looking after his/her finances | 0.127 | -0.043 | 0.223 | 0.778 |
| Things taking longer than they used to | 0.094 | 0.219 | 0.405 | 0.515 |
| Getting in touch with people | -0.103 | -0.152 | 0.508 | 0.003 |
| Not having enough company | 0.132 | 0.067 | 0.675 | 0.047 |
| Not being able to help other people | -0.024 | 0.066 | 0.666 | 0.131 |
| Not playing a useful part in things | 0.045 | 0.043 | 0.679 | 0.208 |
| His/her physical health | -0.025 | -0.003 | 0.698 | 0.263 |

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.

a. Rotation converged in 5 iterations.

Table 3. Reliability Statistics

| Cronbach's Alpha | N. of items |
|------------------|-------------|
| .82              | 31          |

As shown in Table 3, Cronbach's Alpha is .82 it is acceptable.
Finally, in order to evaluate convergent and divergent validity, we used Spearman’s correlation coefficient by comparing the total scores obtained from the various instruments of the study. Table 4 shows the scores obtained from the various correlations.

The correlation between Demqol-Proxy and QoL-AD was positive and significant (C=.190; p.<.05) while the correlation between Demqol-Proxy and CBI is negative and not significant (C=-.096; p.>.05).

Discussion

We have select a theoretical model of 4 factors. We have found 4 factors differently from the original version (14). In the original version, the 5 factors were:
- Cognition
- Negative emotion
- Positive emotion
- Daily activity
- Membership

In our Italian model, we have point out a model of 4 factors in which Positive emotions and Negative emotions factors become a unique element.

So, for the Italian version factors extracted of the scale are
- Cognition [Factor number 2]
- Negative and Positive emotion [Factor number 1]
- Daily activity [Factor number 4]
- Membership [Factor number 3]

The total explained Variance was almost 51% and results was considerable.

A good reliability was found, Cronbach’s Alpha is 0.825, this data was congruent with also the Spanish version of DEMQoL-Proxy (16).

Our Italian version of the DEMQOL-PROXY show valid psychometric characteristics: reconfirming the original version (14) and adaptations produced so far (15-18). In this paper, we have completed our Italian pre-validation (7,20) and we have added: Structural validity, convergent and divergent validity have been explored and satisfied criteria.

We have also compared 3 tools to explore validity of DEMQoL-Proxy. On one hand, we have produced correlation between total score of each one tools. In this way, we have explored Convergent Validity thanks to the correlation between DEMQoL-Proxy and QoL-AD (both instruments assess construct of QoL for people affected by Dementia). On the other hand, we have tested Divergent Validity with the correlation between DEMQoL-Proxy e CBI (both instruments assess different construct of QoL for people affected by Dementia).

Finally, about the comparison between professional caregivers and non-professional caregivers, results obtained allow to consider that DEMQoL-Proxy is able to detect differences between perspective of professional caregiver and not-professional about QoL of patients. So, can be relevant respect and take of different point of view. This result must be re-tested and re-confirmed by future research.

Conclusions

The DEMQOL-PROXY could be in Italy an important tool dedicated from mild to moderate dementia (with 10 to 20 MMSE), in order to assess the QoL from the caregiver perspective. Our proposed pilot Italian version of the DEMQOL-PROXY reconfirm good psychometric properties: its structure and the results it leads to are similar to the original version (14) and to the other translations produced so far (15-18). In this paper, we have completed our Italian pre-validation (7,20) and we have added:

**Table 4. Spearman’ Rho**

| Spearman's Rho | DEMQoLTOT | QOLADTOT | CBITO'T | CBITO'T |
|----------------|-----------|----------|---------|---------|
| Correlation Coefficient | 0.190*  | -0.096   |         |         |
| Sig. (2-tailed)            | 0.011    | 0.200    |         |         |
| N                           | 180      | 180      |         |         |
Structural validity, convergent and divergent validity have been explored and satisfied criteria.

DEMQOL-PROXY in fact, is an instrument able to explore QoL for patients from mild to moderate dementia. This construct is a fundamental element to understand how to improve patient’s experience (14). DEMQOL-PROXY application could be helpful to better manage patients with a level of dementia from mild to moderate (with 10 to 20 MMSE). This questionnaire can be utilized by non-professional caregiver and professional caregiver.

Some limitations can be considered: size of sample, origin of sample (Caregivers were recruited from almost all from one Italian Region).

Implications for future research; could be interesting to go into detail different perspective of caregivers. So, detect differences between professional caregiver and not-professional point of view about QoL of patients will be a productive data to improve clinical setting.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement, etc.) that might pose a conflict of interest in connection with the submitted article

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Correspondence:
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Alessandra Miraglia Raineri
Department of Health Sciences, Psychology and Psychiatry Unit, University of Florence
Florence, Italy
Via di San Salvi n. 12, cap Florence; Italy
E-mail: miraglia83@gmail.com