Epilepsy & Behavior xxx (xxxx) 109132

Contents lists available at ScienceDirect

Epilepsy & Behavior

journal homepage: www.elsevier.com

Cultural adaptation and psychometric properties of the Patient-weighted Quality of Life in Epilepsy 31 Inventory (QOLIE-31P) in Argentina

Mercedes Sarudiansky PhD [a, b, *], Alejandra Inés Lanzillotti PhD [a, b], María Agostina Gerbaudo [b, c], Camila Wolfzun [a, b], Silvia Kochen MD, PhD [a, e, f], Ernesto Stivala MD, PhD [d, g], Luciana D'Alessio MD, PhD [a, d, g], Guido Pablo Korman PhD [a, b]

[a] National Scientific and Technical Research Council of Argentina, Argentina
[b] University of Buenos Aires, School of Psychology, Argentina
[c] National Interuniversity Council of Argentina (CIN), Argentina
[d] University of Buenos Aires, School of Medicine, Argentina
[e] Arturo Jauretche University, Argentina
[f] ENyS, CONICET
[g] Institute of Cellular Biology and Neurosciences E de Robertis (IBCN-CONICET

ARTICLE INFO

Article history:
Received 28 November 2022
Received in revised form 25 January 2023
Accepted 1 February 2023

Keywords:
QOLIE-31P
Psychometric Properties
Cultural Adaptation
Epilepsy
Argentina

ABSTRACT

Objective: This study presents the cultural and linguistic adaptation and psychometric properties of the Argentine version of the Quality of Life in Epilepsy Inventory (QOLIE-31P) scale.
Methods: An instrumental study was carried out. A version of QOLIE-31P translated into Spanish was provided by the original authors. To assess the content validity, evaluation of expert judges was requested, and the degree of agreement was determined. The instrument was administered to 212 people with epilepsy (PWE) of Argentina, together with the BDI-II, B-IPQ and a sociodemographic questionnaire. A descriptive analysis of the sample was carried out. Discriminative capacity of the items was performed. Cronbach's alpha was calculated to assess reliability. To study the dimensional structure of the instrument, a confirmatory factorial analysis (CFA) was performed. Convergent and discriminant validity was tested through mean difference tests, linear correlation, and regression analysis.
Results: Aiken's V coefficients ranged between .90 and 1 (acceptable), which allows to state that a conceptually and linguistically equivalent version of the QOLIE-31P was reached. Cronbach's Alpha of 0.94 was obtained for the Total Scale (optimal). As a result of CFA, 7 factors were obtained, being the dimensional structure similar to the original version. Also, unemployed PWE reported significant lower scores than employed PWE. Finally, QOLIE-31P scores negatively correlated with depression symptom severity and negative illness perception.
Conclusion: The Argentine version of the QOLIE-31P is a valid and reliable instrument, presenting good psychometric properties, such as high internal consistency and a dimensional structure similar to that of the original version.

1. Introduction

The evaluation of the quality of life (QOL) has gained interest in recent decades in the biomedical field [1,2]. In this context, QOL can be understood as how individuals perceive "their position in life in the context of the culture and value systems in which they live, and the relation to their goals, expectations, standards and concerns" [3]. Despite the fact that it is a construct whose definition often presents difficulties [4], it is one of the most used variables in outcome studies of health interventions -for example, RCTs- [1].

With the intention of getting patients' perspectives regarding the impact of illness on their lives, different instruments have been developed to assess their subjective perception of quality of life. However, given the long-range scope of the construct and the particular aspects of the problems arising from each illness process, in the last 30 years, disease-specific psychometric instruments have been developed to assess the quality of life in specific pathologies [1,5]. In this context, Devinsky et al. [6] developed the Quality of Life in Epilepsy 89 Inventory (QOLIE-89), an instrument to assess QOL specifically in patients with epilepsy. Based on the generic RAND-36 QOL scale [7], the authors added different items to investigate specific problems reported by patients with

* Corresponding author at: Instituto de Investigaciones en Psicología, Lavalle 2353, C1052AAA Buenos Aires, Argentina.
E-mail address: msarudiansky@conicet.gov.ar (M. Sarudiansky).

https://doi.org/10.1016/j.yebeh.2023.109132
1525-5050/

epilepsy, such as epilepsy-oriented health perception, social function, driving limitations, seizure worry, and medication effects, among other aspects [6].

In light of the need for a brief instrument to assess QOL that focuses on areas of concern for people with epilepsy (PWE) and also facilitates the process of adaptation to different cultures, Cramer et al. [8] developed a shortened version, the QOLIE-31 Inventory. This is a 31-item instrument, based on a reflective model, which is composed of seven domains (mood, daily activities, energy/fatigue, cognition, seizure worry, medication effects, and overall quality of life). Such domains cover both general QOL and epilepsy-specific topics, during the past four weeks. An item evaluating overall health status was also added, based on the Euroqol (EQ) [9], although it does not contribute to the total score. More recently, the same working group published an updated version, the Patient-weighted QOLIE-31 (QOLIE-31P). This new version has minimal modifications -such as the names of some of the subscales- and also adds items to assess the importance patients give to each domain [10]. The total scores of each domain are calculated according to the instructions in the Scoring Manual [11].

Since its publication, different versions of the QOLIE-31 and QOLIE-31P have been culturally adapted worldwide, for example in Spain [12], Lithuania [13], and Italy [14], just to name a few. However, to date, no cultural and psychometric adaptations of the QOLIE-31P have been made in Argentina, which results in a knowledge gap in the field. For this reason, this study aims to present the results of the adaptation and validation process of the QOLIE-31P for PWE in Argentina together with the results of the psychometric properties assessment.

2. Methods

2.1. Study design

This is an instrumental study [15] carried out in two stages. The guidelines proposed by COSMIN were followed to guarantee the quality of the study [16].

2.1.1. Stage 1 - Linguistic and conceptual adaptation

At this stage, authorization was requested from the authors of the original instrument [10], who provided us with a translated version of it. Besides, they reported that the translation process had been carried out by the company "Oxford Outcomes", which certified the completion of both a forward and back translation. This version was reviewed by the research team of the UBACyT 20020170100274BA project, taking into account the relevant modifications in relation to those idioms and local expressions that are specific to the cultural context to which the test has been adapted (Argentina). Subsequently, in order to assess the content validity, the evaluation of expert judges was requested. The evaluation form is presented in the supplementary material. In addition, at this stage, the wording of the instructions and items was revised again, based on the expert judges' suggestions.

2.1.2. Stage 2 - Analysis of the psychometric properties

a. Study setting

In this second stage, between 2020 and 2022, PWE were invited to participate through two epilepsy reference centers in Buenos Aires, Argentina (Ramos Mejía Hospital and El Cruce Hospital) and contact via social media groups of PWE from Argentina. The inclusion criteria were the following: the participants had to be adults (18 years of age or older), they had to be residents of Argentina, speak Spanish as a first language, report a diagnosis of epilepsy given by a neurologist, and express their willingness to participate in the study. Participants with reading and writing difficulties and those who did not understand the Spanish language were excluded.

b. Sample

The sample consisted of 212 participants (73.4% women), with a mean age of 34.71 (SD = 10.26, min = 18, max = 64). Out of all participants, more than half (53%) were unemployed at the time of the evaluation. Regarding the educational level, 44% expressed having reached or finished High School. More details about the sociodemographic and clinical characteristics of the sample are found in Table 1.

c. Instruments

In addition to the revised version of the QOLIE-31P obtained in Stage 1, the following instruments were administered:

- Sociodemographic and epilepsy questionnaire: the Questionnaire was conducted *ad hoc* to inquire about sociodemographic variables of the participants (sex, age, educational level, occupation) and clinical variables (age of onset of the disease, seizure frequency, current antiepileptic medication).
- Brief Illness Perception Questionnaire (B-IPQ) [17,18]. It is a self-report instrument that assesses the perception of illness according to the "Common Sense Model" [19,20]. It contains eight quantitative items that can be answered on a scale from 0 to

Table 1
Sociodemographic and clinical characteristics of the sample.

Age (years)	
M ± SD	34.71 ± 10.26
Min-Max	18–64
Age when first seizure occurred (years)	
M ± SD	16.53 ± 10.42
Min-Max	0–52
	N (%)
Gender	
Female	155 (73.1)
Male	56 (26.4)
Other	1 (0.5)
Education	
Incomplete Elementary	6 (2.8)
Complete Elementary	12 (5.7)
Incomplete High School	36 (16.9)
Complete High School	57 (26.9)
Incomplete Tertiary	20 (9.4)
Complete Tertiary	27 (12.7)
Incomplete college	22 (10.4)
Complete college	32 (15.1)
Marital status	
Married	121 (57.1)
Single	78 (36.8)
Divorced	12 (5.7)
Widow	1 (0.5)
Occupation	
Unemployed	99 (46.7)
Employee	113 (53.3)
Seizure frequency	
Daily/weekly	91 (42.9)
Monthly/Every 6 month	48 (22.6)
Annual/Seizure-free	71 (33.5)
Do not know/Missing	2 (0.9)
Medication	
Monodrug	58 (27.3)
Polymedicated	126 (59.4)
levetiracetam	85 (21.0)
lamotrigine	63 (15.6)
valproate	52 (12.9)
carbamazepine	36 (8.9)
topiramate	19 (4.7)
benzodiazepines	40 (9.9)
oxcarbazepine	16 (4.0)
phenytoin	17 (4.2)
phenobarbital	15 (3.7)
lacosamide	19 (4.7)
clobazam	28 (6.9)
cannabis	8 (2.0)
other (gabapentin, pregabalin, brivaracetam)	6 (1.5)
Missing	28(13.2)

10 and a qualitative item that evaluates hypotheses of causality about diseases. The highest scores of the quantitative items reflect a less healthy perception of the disease.

– Beck Depression Inventory - Second Edition (BDI-II) [21,22]. It is a 21-item multiple-choice self-report instrument that assesses the severity of depressive symptomatology in individuals aged between 13 and 80 years. Higher scores indicate further severity of depressive symptomatology.

2.2. Ethical aspects

This study was conducted in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) and has the endorsements of the respective Ethics Committees of both hospitals ("Ramos Mejía" and "El Cruce"), and the endorsement of the Committee of Ethics of the Faculty of Psychology of the University of Buenos Aires. All participants signed an informed consent which detailed the characteristics of this study. Moreover, the participants' data has been protected to ensure their confidentiality.

2.3. Data analysis

2.3.1. First Stage

To evaluate the degree of agreement of the expert judges regarding the pertinence, clarity, sufficiency, and relevance of the items, Aiken's V coefficient [23] was used.

2.3.2. Second Stage

A descriptive analysis of the sample and the administered scales' scores was carried out, through central tendency, variability, and position measures. To calculate the missing items, the procedure indicated in the QOLIE-31P Scoring Manual was followed.

To evaluate the discriminative capacity of the items, the extreme comparison method was used [24]. For this purpose, the sample was divided into quartiles with respect to the total score of the QOLIE-31P. Subsequently, a t-test was used to compare the values of the items of the extreme groups (Q1 and Q3). Items that adequately discriminate are expected to present statistically significant differences between these two scores.

To assess reliability, Cronbach's alpha was calculated for the entire test and each of its subscales. The Cronbach's alpha of 0.7 was the criterion deemed acceptable.

To study the dimensional structure of the instrument, a factorial analysis was performed, using robust maximum likelihood estimation (multivariate non-normal), with an eigenvalue threshold >1 for the inclusion of factors. To measure sample adequacy, the Kaiser-Meyer-Olkin test was used (acceptable KMO level ≥ 0.5). Moreover, the sample size can be considered fair [25–27].

A multi-trait scaling analysis was performed by calculating Pearson's correlations between the scores of each item and the total score of each subscale. To consider good construct validity, it is expected that each item more strongly correlates with the subscale it integrates, compared to the rest of the subscales [1].

A comparison analysis of groups was carried out according to employment situation (employed/unemployed) and seizure frequency (daily/weekly, monthly/half-yearly, and annual/seizure-free). The total scores of the scale and the original dimensions were compared. Unemployed PWE and those with higher seizure frequency were expected to have lower scores on the total scale and/or on some specific subscales. Student's t-tests were performed for two-group comparisons and one-way ANOVA for variables of more than two groups. Tukey's post hoc tests were used to determine pairwise differences with correction for multiple comparisons.

To assess convergent validity, total BDI-II and B-IPQ scores were calculated, expecting a negative association between these measures and QOLIE-31P scores. For this purpose, correlation analysis (Pearson's r) and simple linear regression were performed.

For all statistical tests, we used a level of significance of 5% ($p < 0.05$). For psychometric and statistical analysis, software R for Windows (version 4.2.2) was used.

3. Results

3.1. Linguistic adaptation and content validity

Based on the version translated into Spanish provided by the original authors and the review by the researchers and expert judges, minimal modifications were made, which included verb tenses as well as some editorial and grammatical adjustments. These are listed in the supplementary material.

Regarding content validity by expert judges, Aiken's V coefficients ranged between 0.90 and 1, values that are considered acceptable [23,28]. Further details will be found in the supplementary material. In this way, a conceptually and linguistically equivalent version of the QOLIE-31P was reached, understandable to the target population.

3.2. Scores and subscales

Considering the entire sample, the final mean score of the QOLIE-31P was 53.02, SD = 17.49, min = 1.71, max = 94.29. Regarding item Q38, which assesses Overall Health, a final mean score of 56.97, SD = 23.53, min = 0, max = 100 was obtained. The scores for each of the subscales are detailed in Table 2.

3.3. Item analysis and internal consistency

The differences between groups Q1 and Q3 in relation to the mean of each item were significant for all items ($p < .01$). This implies that all the items discriminate adequately. More details are presented in the supplementary material.

Table 2
Cronbach's Alpha and mean scores for each of the subscales (N = 212).

Subscales	Item numbers	Cronbach's alpha	Mean	SD	Skewness	Kurtosis	Mean distress scores (SD) (*)
Energy/Fatigue (E/F)	2, 3, 4, 5	0.81	46.39	21.39	0.12	−0.15	53.35(28.63)
Mood (MOO)	7, 8, 9, 10, 11	0.79	53.68	20.05	0.18	−0.58	52.61(27.40)
Daily activities (ACT)	13, 14, 15, 16, 17	0.83	52.06	27.96	0.01	−0.97	53.77(29.81)
Cognition (COG)	19, 20, 21, 22, 23, 24	0.89	45.66	27.07	0.21	−0.96	49.29(31.78)
Medication effects (MED)	26, 27, 28	0.79	50.16	30.83	−0.06	−1.09	54.91(30.73)
Seizure worry (SW)	30, 31, 32, 33, 34	0.79	33.60	26.22	0.72	−0.32	44.63(28.94)
Overall Quality of Life (OQoL)	1, 36	0.72	60.66	20.58	−0.61	0.36	48.99(26.28)
Total score (**)	–	0.94	53.02	17.49	−0.16	−0.29	–

(*) E/F: Item 6; MOO: Item 12; ACT: Item 18; COG: Item 25; MED: Item 29; SW: Item 35; OQoL; Item 37.
(**) According to Scoring Manual: Sum of Sub-Scale Weighted Totals (A-G) divided by the sum of Distress Scores (A-G), multiplied by 100.

Regarding the reliability of the test, a Cronbach's Alpha of 0.94 was obtained for the Total Scale -optimal-, and Alpha values between 0.72 and 0.89 -acceptable- for the different scales (see Table 2).

3.4. Validity analysis of QOLIE-31P

3.4.1. Dimensionality and construct validity

The KMO test was 0.883 and the significance of the Bartlett sphericity test was less than 0.001, so it was appropriate to perform a factor analysis.

A confirmatory factor analysis was carried out to determine the goodness of fit of the original seven-factor model ("Model 1") [8,11]. The following results were obtained: $\chi 2 = 833.395$, $p < .001$; CFI = 0.84; TLI = 0.82; RMSEA = 0.078; SRMR = 0.081, AIC = 59357.048. Taking into account the factor loadings (Table 3), another seven-factor model was proposed ("Model 2"). In this case, considering the sample size, factor loadings ≥0.364 were accepted for the inclusion of items in one of the factors [29], after oblique rotation (Oblimin). For this reason, item 36 was discarded. In Model 2 the items were grouped in the same way as Model 1 in three factors ("Cognition", 6 items: 19, 20, 21, 22, 23, and 24; "Medication effects", 3 items: 26, 27, and 28; "Seizure worry", 5 items: 30, 31, 32, 33, and 34). Also, the items that were originally grouped into the dimensions "Daily activities" and "Overall Quality of Life" were grouped into a single factor ("Activities/Overall QOL", 7 items: 1, 13, 14, 15, 16, and 17). On the other hand, out of the items that were originally grouped into the "Energy/Fatigue" and "Mood" dimensions, 4 items were grouped into a single factor ("Positive mood/Energy", items 2, 3, 9, and 11); 2 items from the "Energy/Fatigue" dimension were independently grouped into another factor ("Fatigue", items 4 and 5); and 3 items from the "Mood" dimension were grouped into another factor ("Negative mood", items 7, 8 and 10) (see Fig. 1). Model 2 fit measures were acceptable: $\chi 2 = 591.083$, $p < .001$; CFI = 0.91; TLI = 0.90; RMSEA = 0.059; SRMR = 0.066; AIC = 57339.423. Thus, Model 2 showed a better fit than Model 1, approaching acceptable values of fit indices, and a lower value of the Akaike criterion [30,31].

The multi-trait scaling analysis showed that each item has a stronger correlation with the scale they comprise, compared to the other subscales, which supports a good construct validity (Table 4).

3.4.2. Discriminant validity

On the other hand, considering the employment situation of participants, significant differences were found in the mean scores of each subscale as well as in the total mean score. For all cases, lower mean scores were found in those unemployed people. It should also be noted that, out of the proportion of unemployed people, 55.2% expressed that epilepsy was the reason for their unemployment.

Considering patient-reported seizure frequency, significant differences were found in the "Activities" subscale ($F(2, 207) = 8.567$, $p < .001$, $\eta 2 = 0.076$) between those PWE with an annual seizure frequency or seizure-free (M = 62.31) and those who reported experiencing daily/weekly (M = 44.67) or monthly/semester (M = 50.58) seizures. Additionally, significant differences were found in the "Overall Quality of Life" subscale ($F(2, 207) = 10.714$, $p < .001$, $\eta^2 = 0.094$) between patients with a daily/weekly seizure frequency (M = 54.20) and those who reported a more spaced seizure frequency ($M_{month/semester} = 62.50$; $M_{Annual/Seizure\_free} = 68.42$).

3.4.3. Convergent validity

Correlation analysis between QOLIE-31P and BDI-II and B-IPQ scales showed a negative linear correlation with the BDI ($r = -0.61$; $p = .001$) and with the B-IPQ ($r = -0.64$; $p = .001$).

Table 3
Factor analysis. Pattern matrix after Oblimin rotation (N = 212).

Item number	Communalities	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7
1	0.334	−0.050	−0.008	0.180	−0.094	**−0.440**	0.006	−0.082
2	0.757	0.038	−0.022	**0.832**	0.000	−0.064	0.044	0.052
3	0.714	−0.082	−0.244	**0.761**	−0.069	−0.031	0.040	0.166
4	0.864	0.159	**−0.794**	0.065	−0.036	−0.003	0.131	−0.066
5	0.824	0.081	**−0.753**	0.100	−0.056	−0.137	−0.039	−0.107
7	0.438	0.040	−0.183	−0.101	0.009	−0.007	0.216	**−0.488**
8	0.845	0.102	−0.049	0.076	−0.001	−0.048	−0.037	**−0.836**
9	0.437	−0.028	0.064	**0.569**	−0.049	0.029	0.017	−0.250
10	0.668	0.089	−0.065	0.252	0.006	−0.104	0.007	**−0.604**
11	0.519	0.161	−0.005	**0.641**	−0.021	0.035	−0.027	−0.094
13	0.634	−0.012	−0.039	0.070	0.092	**−0.728**	0.085	−0.096
14	0.713	−0.047	−0.077	−0.068	−0.060	**−0.829**	−0.035	−0.098
15	0.529	0.078	−0.074	−0.081	0.017	**−0.737**	−0.068	0.075
16	0.476	0.282	0.160	0.020	−0.041	**−0.497**	0.098	0.059
17	0.459	0.071	0.137	0.208	−0.174	**−0.385**	0.194	0.037
19	0.633	**0.572**	−0.035	0.020	−0.043	−0.238	0.096	−0.047
20	0.671	**0.812**	0.019	0.075	0.017	−0.067	0.003	0.104
21	0.684	**0.841**	−0.035	0.023	0.058	0.034	−0.047	−0.053
22	0.533	**0.632**	−0.149	−0.018	−0.048	−0.006	−0.024	−0.086
23	0.544	**0.604**	−0.081	−0.009	−0.139	−0.011	−0.032	−0.113
24	0.642	**0.728**	0.035	−0.025	−0.113	0.054	0.119	−0.016
26	0.728	−0.085	−0.074	0.005	**−0.880**	−0.059	−0.058	0.071
27	0.709	0.111	−0.020	0.032	**−0.814**	0.072	−0.072	0.002
28	0.379	0.075	0.069	0.004	**−0.516**	0.016	0.147	−0.048
30	0.529	−0.009	−0.032	0.089	0.080	−0.018	**0.736**	0.058
31	0.585	−0.058	−0.096	−0.040	−0.080	0.041	**0.743**	−0.064
32	0.417	0.076	0.042	−0.014	0.011	0.090	**0.655**	0.026
33	0.359	0.049	0.087	−0.086	−0.123	−0.139	**0.388**	−0.202
34	0.502	−0.014	−0.014	0.043	−0.018	−0.126	**0.630**	−0.040
36	0.509	0.128	−0.116	0.295	−0.025	−0.339	0.129	−0.054

Note: *Items comprising respective subscales are presented in bold.*
Factor 1: "Cognition"; Factor 2: "Fatigue"; Factor 3: "Positive mood"; Factor 4: "Medication effects"; Factor 5: "Daily activities"; Factor 6: "Seizure worry"; Factor 7: "Negative mood".

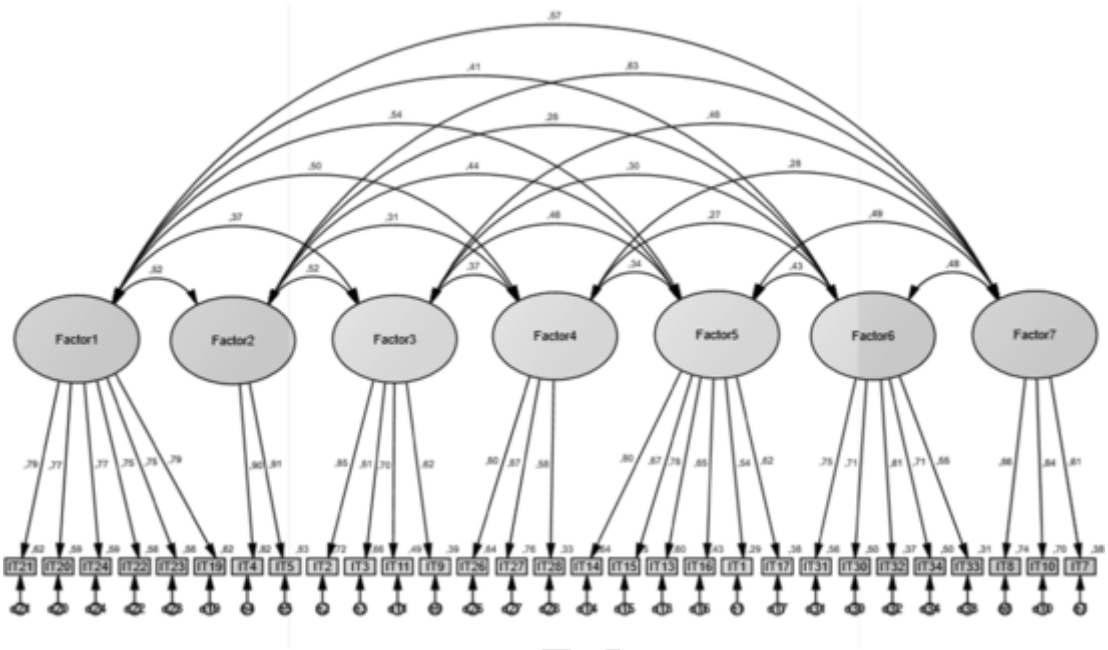

Fig. 1. "Model 2" - Seven-factor model - QOLIE31-P.

Table 4
Multitrait-scaling analysis. Pearson's correlation coefficients between items and subscales (N = 212).

Item number (subscale)	E/F	MOO	ACT	COG	MED	SW	OQoL	Total
1 (OQoL)	0.350**	0.365**	0.472**	0.272**	0.245**	0.216**	**0.877****	0.563**
2 (E/F)	**0.766****	0.510**	0.375**	0.299**	0.269**	0.232**	0.467**	0.525**
3 (E/F)	**0.814****	0.445**	0.296**	0.201**	0.264**	0.159*	0.394**	0.458**
4 (E/F)	0.**804****	0.538**	0.306**	0.473**	0.255**	0.278**	0.398**	0.555**
5 (E/F)	0.**825****	0.529**	0.356**	0.418**	0.247**	0.166*	0.391**	0.547**
7 (MOO)	0.296**	**0.659****	0.210**	0.323**	0.153*	0.380**	0.281**	0.439**
8 (MOO)	0.442**	**0.828****	0.332**	0.469**	0.216**	0.352**	0.375**	0.594**
9 (MOO)	0.475**	**0.689****	0.236**	0.228**	0.245**	0.220**	0.325**	0.464**
10 (MOO)	0.534**	0.**831****	0.404**	0.445**	0.253**	0.362**	0.416**	0.623**
11 (MOO)	0.568**	**0.670****	0.286**	0.361**	0.262**	0.189**	0.429**	0.510**
13 (ACT)	0.400**	0.403**	**0.784****	0.350**	0.166*	0.327**	0.539**	0.586**
14 (ACT)	0.377**	0.363**	**0.805****	0.366**	0.245**	0.274**	0.494**	0.612**
15 (ACT)	0.276**	0.209**	**0.742****	0.334**	0.156*	0.156*	0.380**	0.482**
16 (ACT)	0.228**	0.271**	**0.791****	0.457**	0.295**	0.299**	0.381**	0.564**
17 (ACT)	0.344**	0.322**	**0.738****	0.372**	0.376**	0.376**	0.438**	0.577**
19 (COG)	0.409**	0.458**	0.531**	**0.807****	0.362**	0.405**	0.478**	0.693**
20 (COG)	0.338**	0.354**	0.428**	**0.817****	0.350**	0.273**	0.317**	0.576**
21 (COG)	0.337**	0.410**	0.349**	**0.825****	0.295**	0.237**	0.301**	0.548**
22 (COG)	0.377**	0.405**	0.330**	**0.798****	0.306**	0.239**	0.341**	0.557**
23 (COG)	0.369**	0.412**	0.378**	**0.800****	0.389**	0.268**	0.306**	0.576**
24 (COG)	0.277**	0.401**	0.373**	**0.819****	0.407**	0.355**	0.289**	0.593**
26 (MED)	0.298**	0.222**	0.280**	0.325**	**0.867****	0.173*	0.303**	0.507**
27 (MED)	0.309**	0.267**	0.257**	0.428**	**0.879****	0.199**	0.246**	0.547**
28 (MED)	0.199**	0.284**	0.281**	0.341**	**0.764****	0.320**	0.211**	0.498**
30 (SW)	0.230**	0.280**	0.264**	0.226**	0.142*	**0.751****	0.275**	0.372**
31 (SW)	0.236**	0.325**	0.259**	0.271**	0.212**	**0.801****	0.224**	0.407**
32 (SW)	0.090	0.214**	0.152*	0.221**	0.143*	**0.728****	0.173*	0.307**
33 (SW)	0.154*	0.323**	0.324**	0.330**	0.277**	**0.684****	0.307**	0.485**
34 (SW)	0.269**	0.372**	0.377**	0.300**	0.224**	**0.746****	0.259**	0.462**
36 (OQoL)	0.554**	0.511**	0.540**	0.457**	0.291**	0.371**	**0.892****	0.712**

Note: *Items comprising respective subscales are presented in bold.*
E/F: Energy/Fatigue, MOO: Mood, ACT: Daily Activities, COG: Cognition, MED: Medication effects, SW: Seizure worry, and OQoL: Overall quality of life.
*p < .05 **p < .01.

Additionally, it was found that the total score on the QOLIE-31P scale is a significant predictor of both the severity of depressive symptoms ($F(1, 119) = 69.107$, $p < .001$, $\beta = -0.424$, $t(gl) = -8.313$, $p < .001$) and illness perception ($F(1, 210) = 145.071$, $p < .001$, $\beta = -0.462$ $t(gl) = -12.045$, $p < .001$). In this regard, quality of life explains 36.7% of the severity of depressive symptoms and 40.9% of illness perception.

4. Discussion

One of the aims of the present study was to evaluate the psychometric properties of the Argentine version of the QOLIE-31P. The results suggest that this version of the instrument has a high internal consistency and reliability, similar to its original version [8,10] and to other versions already adapted to other contexts [12,13,32].

Regarding the dimensionality of the instrument, when comparing the goodness-of-fit indices of two seven-factor models ("Model 1", the original one proposed by the authors [8,10] and an alternative model, "Model 2"), we found that the latter presented better-fit indicators. Nevertheless, this should not affect the general interpretation of the instrument, as seen in other adaptations of the QOLIE-31P [13,14,32]. Although both models present many similarities, some dimensions of Model 2 do not correspond to the original ones and even one item (item 36) had to be discarded due to its low factor load, in order to achieve an adequate fit of the model [29]. The latter could be due to the fact that this item corresponded to the "Overall QOL" subscale, which was not maintained in Model 2. Given that this item explores very general aspects of QOL ("How has your quality of life been in the last 4 weeks?"), it is consistent with this item not being fully integrated into any particular factor.

In fact, these differences could be considered as a possibility for having an in-depth understanding of some subscales. Such is the case of "Mood" and "Energy/Fatigue", in which we see a regrouping of some of their items into a single factor, which we called "'Positive' Mood": These items correspond to questions about happiness ("During the last 4 weeks, how often did you feel happy") and vitality ("During the last 4 weeks, how often did you feel full of vitality?"). In turn, those items referring to sadness and discouragement were grouped into the "'Negative' mood" factor ("During the last 4 weeks, how often did you feel discouraged and sad?"). On the other hand, items 4 ("During the last 4 weeks, how often did you feel exhausted?") and 5 ("During the last 4 weeks, how often did you feel tired?"), that corresponded to "Energy/Fatigue", were grouped into another differentiated factor, which we proposed to call "Fatigue". Thus, the distinction between "positive" mood and "negative" mood would allow the possibility of exploring the "Mood" variable in greater depth in the context of the QOL. Although the distinction between "positive" and "negative" emotions is debatable, it has already been used in other studies that investigate the association between these different dimensions of mood with other variables, such as empathy and burnout [33], emotional regulation [34], or impulsivity [35].

On the other hand, the items of the original dimensions "Daily activities" ("During the last 4 weeks, how often has your health limited your social activities [such as visiting friends or close relatives]?") and "Overall QOL" ("In general terms, how would you rate your quality of life?") were regrouped in this version into a single dimension: "Activities/Overall QOL." This regrouping of "Overall QOL" with other dimensions is consistent with previous literature, as other adaptations of the instrument also had a similar regrouping in this dimension [13,36,37].

One aspect to take into account in this adaptation process is that the results of the multi-trait scaling analysis presented very high correlations between the items of each dimension with the total of each dimension that they comprise, following the original structure (Model 1). This has also been reported in other studies [13,32,36]. In the same way, we believe that the present results account for adequate construct validity.

As expected, our results support the hypothesis that QOLIE-31P scores would be negatively correlated with the depressive symptom scale scores. These data support the validity of the instrument. In addition, different studies with patients with epilepsy show the importance of the association between these two variables. First, PWE present high rates of depression in relation to other mental disorders [38–40] and also in comparison with the general population [41]. Furthermore, as some authors have suggested [42] depression is a better predictor of QOL in PWE than other factors, such as those related to seizure frequency or its characteristics.

This study also sought to account for the convergent validity of the QOLIE-31P in relation to illness perception. In this case, a negative illness perception (higher scores on the B-IPQ) would be associated with lower scores on QOL. The relationship between illness perception and QOL has been studied in different pathologies, such as cancer [43,44], kidney disease [45–47], and heart disease [48]. In the specific case of epilepsy, Shallcross et al. [49] found that illness perceptions act as mediators between depression and QOL, supporting the idea that psychological/social factors have a significant and even more important impact on QOL than some clinical variables of epilepsy.

In fact, when comparing the QOLIE-31P scores according to seizure frequency, we only found significant differences in two subscales ("Activities" and "Overall QOL", which were grouped into a single dimension in our factor analysis). Although we expected significant associations with more subscales, we think that there may be some factors that could explain why this does not occur in our sample. On the one hand, what was previously mentioned regarding seizure frequency as a predictor variable of QOL [42]. On the other hand, there could also be other variables at play that were not considered in this study, such as seizure severity, duration, or the time of day in which they occur. Therefore, these aspects should be analyzed and deepened in subsequent studies.

Another hypothesis was that we were going to find significant differences in the scores between those people with a job or occupation and those who were unemployed. In fact, unemployed participants presented lower scores in almost all subscales, including the total score. This is consistent with what has been reported in other adaptations of the QOLIE-31P [13,36]. Employment is one of the most relevant concerns for PWE, given that PWE reports difficulty in obtaining and/or keeping a job, rejection by employers, or restrictions regarding the types of work they can access [50,51]. Additionally, some authors suggest that unemployed PWE feel more affected by stigma (related to epilepsy) than those who are employed [52].

Regarding the mean scores of the subscales of the instrument, the score of the "Seizure worry" scale stands out, because it is the lowest mean score compared to the rest of the subscales. This is consistent with what has been found in other studies [32,53]. This could be due to the fact that a large number of the participants in this study attended tertiary centers of epilepsy, and those PWE with refractory epilepsy or high seizure frequency might be over-represented. We believe that this aspect should be studied in greater depth by future research.

This study has several limitations. On the one hand, this sample has a majority of women. On the other hand, as mentioned before, since most patients were recruited from tertiary centers of epilepsy, patients with drug-resistant epilepsy and/or high seizure frequency may be over-represented.

Another limitation of this study is that, since most of the cross-cultural adaptations of this instrument were carried out with the original version of the QOLIE-31, it could be problematic to conclude when comparing results. In fact, it has been reported that the weighting of the patient in QOLIE-31P tends to decrease the total score [54]. Future studies should carefully analyze these scores to draw correct conclusions. In any case, this aspect also highlights the importance of having local standard scales in the evaluation instruments for each population. For this reason, we believe that the QOLIE-31P adapted to the Argen-

tine population will be a useful instrument to accurately measure QOL in PWE in this cultural context, at a clinical, research, and public policy level. In the future, other parameters that have been set aside in this research should be taken into consideration, such as other sociodemographic variables, type of epilepsy according to the current classification, severity of seizures, and perception of stigma, among others.

5. Conclusion

The Argentine version of the QOLIE-31P presents good psychometric properties, such as high internal consistency and a dimensional structure similar to the one in the original version. Therefore, we consider it to be a valid and reliable instrument that will allow us to evaluate QOL in PWE in Argentina, not only in the clinical and/or therapeutic context but also for clinical research in this population.

Funding

This research was supported by the project UBACyT-20020170100274BA (University of Buenos Aires, Argentina) and by the National Interuniversity Council of Argentina (CIN).

Data sharing statement

The data files corresponding to our analysis are available from the first author on request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

We are very grateful for the significant collaborations of Ivana García (from Espacio Epilepsia Foundation), Brenda Giagante, Silvia Oddo, and Alejandro Pagano.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.yebeh.2023.109132.

References

[1] Fayers PM, Machin D. Quality of Life - The assessment, analysis and interpretation of patient-reported outcomes. 2nd ed., vol. 138. Chichester, UK: Wiley & Sons; 2003. 142 p.
[2] Ronen G.M, Rosenbaum P.L, Boyle M.H, Streiner D.L. Patient-reported quality of life and biopsychosocial health outcomes in pediatric epilepsy: An update for healthcare providers. Available from. Epilepsy Behav [Internet] 2018;86:19–24. https://linkinghub.elsevier.com/retrieve/pii/S1525505018302841.
[3] Whoqol Group. Study protocol for the World Health Organization project to develop a Quality of Life assessment instrument (WHOQOL). Available from. Qual Life Res [Internet] 1993;2(2):153–9. http://www.ncbi.nlm.nih.gov/pubmed/8518769.
[4] Karimi M, Brazier J. Health, Health-Related Quality of Life, and Quality of Life: What is the Difference? Available from. Pharmacoeconomics [Internet] 2016;34(7):645–9. http://link.springer.com/10.1007/s40273-016-0389-9.
[5] de Boer A.G, Spruijt R.J, Sprangers M.A.G, de Haes J.C. Disease-specific quality of life: is it one construct? Available from. Qual Life Res [Internet] 1998;7(2):135–42. http://www.ncbi.nlm.nih.gov/pubmed/9523495.
[6] Devinsky O, Vickrey B.G, Cramer J.A, Perrine K, Hermann B, Meador K, et al. Development of the Quality of Life in Epilepsy Inventory. Available from. Epilepsia [Internet] 1995;36(11):1089–104. http://doi.wiley.com/10.1111/j.1528-1157.1995.tb00467.x.
[7] Hays R.D, Sherbourne C.D, Mazel R.M. The rand 36-item health survey 1.0. Available from: Health Econ [Internet] 1993;2(3):217–27. https://onlinelibrary.wiley.com/doi/10.1002/hec.4730020305.
[8] Cramer J.A, Perrine K, Devinsky O, Bryant-Comstock L, Meador K, Hermann B. Development and Cross-Cultural Translations of a 31-Item Quality of Life in Epilepsy Inventory. Available from. Epilepsia [Internet] 1998;39(1):81–8. https://onlinelibrary.wiley.com/doi/10.1111/j.1528-1157.1998.tb01278.x.
[9] Brazier J, Jones N, Kind P. Testing the validity of the Euroqol and comparing it with the SF-36 health survey questionnaire. Available from. Qual Life Res [Internet] 1993;2(3):169–80. http://link.springer.com/10.1007/BF00435221.
[10] Cramer J.A, Van Hammée G. Maintenance of improvement in health-related quality of life during long-term treatment with levetiracetam. Available from. Epilepsy Behav [Internet] 2003;4(2):118–23. http://linkinghub.elsevier.com/retrieve/pii/S1525505003000040.
[11] QOLIE Development Group. Scoring manual for the QOLIE-31-P: Patient-Weighted Quality of life in epilepsy (v.2). 2013.
[12] Torres X, Arroyo S, Araya S, Pablo J. The Spanish Version of the Quality-of-Life in Epilepsy Inventory (QOLIE-31): Translation, Validity, and Reliability. Available from. Epilepsia [Internet] 1999;40(9):1299–304. https://onlinelibrary.wiley.com/doi/10.1111/j.1528-1157.1999.tb00861.x.
[13] Puteikis K, Mameniškienė R. Psychometric properties of the Lithuanian version of the patient-weighted inventory on quality of life in epilepsy. Available from. Epilepsy Behav [Internet] 2022;130:108648. https://linkinghub.elsevier.com/retrieve/pii/S152550502200097X.
[14] Beghi E, Niero M, Roncolato M. Validity and reliability of the Italian version of the Quality-of-Life in Epilepsy Inventory (QOLIE-31). Available from. Seizure [Internet] 2005;14(7):452–8. https://linkinghub.elsevier.com/retrieve/pii/S1059131105001275.
[15] Montero I, León O.G. A guide for naming research studies in Psychology. Int J Clin Heal Psychol 2007;7(3):847–62.
[16] Gagnier J.J, Lai J, Mokkink L.B, Terwee C.B. COSMIN reporting guideline for studies on measurement properties of patient-reported outcome measures. Available from. Qual Life Res [Internet] 2021;30(8):2197–218. https://link.springer.com/10.1007/s11136-021-02822-4.
[17] Broadbent E, Petrie K.J, Main J, Weinman J. The Brief Illness Perception Questionnaire. Available from. J Psychosom Res [Internet] 2006;60(6):631–7. https://linkinghub.elsevier.com/retrieve/pii/S0022399905004915.
[18] Ponieman M, Wolfzun C, Sarudiansky M. Adaptación lingüística y conceptual del Cuestionario Breve de Percepción de Enfermedad (B-IPQ): presentación de los resultados preliminares de la escala a partir de una prueba piloto en dos centros de epilepsia de Buenos Aires, Argentina. Actas del XIII Congr Int Investig y Práctica Prof en Psicol. 2020;III.
[19] Cameron L, Leventhal H. The Self-Regulation of Health and Illness Behaviour [Internet]. London: Routledge; 2012.
[20] Hagger M.S, Orbell S. A Meta-Analytic Review of the Common-Sense Model of Illness Representations. Available from. Psychol Health [Internet] 2003;18(2):141–84. http://www.tandfonline.com/doi/abs/10.1080/0887044031000813321.
[21] Beck A.T, Steer R.A, Brown G.K. Manual for the Beck depression inventory-II. San Antonio, TX: Psychological Corporation; 1996.
[22] Brenlla M.E, Rodríguez C. Adaptación argentina del Inventario de Depresión de Beck. Buenos Aires: Paidós; 2006.
[23] Aiken L.R. Three Coefficients for Analyzing the Reliability and Validity of Ratings. Available from. Educ Psychol Meas [Internet] 1985;45(1):131–42. http://journals.sagepub.com/doi/10.1177/0013164485451012.
[24] Muñiz J, Fidalgo A, García-Cueto E, Martínez R, Moreno R. Análisis de los ítems. Madrid: La Muralla; 2005.
[25] Comrey A.L. Factor-analytic methods of scale development in personality and clinical psychology. Available from. J Consult Clin Psychol [Internet] 1988;56(5):754–61. http://doi.apa.org/getdoi.cfm?doi=10.1037/0022-006X.56.5.754.
[26] Williams B, Onsman A, Brown T. Exploratory factor analysis: A five-step guide for novices. Available from: Australas J Paramed [Internet] 2010;8(3). http://ajp.paramedics.org/index.php/ajp/article/view/93.
[27] Kyriazos T.A. Applied Psychometrics: Sample Size and Sample Power Considerations in Factor Analysis (EFA, CFA) and SEM in General. Available from. Psychology [Internet] 2018;9(8):2207–30. http://www.scirp.org/journal/doi.aspx?DOI=10.4236/psych.2018.98126.
[28] Aiken L.R. Tests Psicológicos y Evaluación. CDMX, México: Pearson Education; 2003. p. 544.
[29] Stevens J.P. Exploratory and Confirmatory Factor Analysis. In: Stevens J.P, editor. Applied Multivariate Statistics for the Social Sciences. New York, NY: Routledge; 2009. p. 325–94.
[30] Akaike H. A Bayesian analysis of the minimum AIC procedure. Ann Inst Stat Math 1978;30:9–14.
[31] Huang P.-H. Asymptotics of AIC, BIC, and RMSEA for Model Selection in Structural Equation Modeling. Available from. Psychometrika [Internet] 2017;82(2):407–26. http://link.springer.com/10.1007/s11336-017-9572-y.
[32] Todorova K.S, Velikova V.S, Tsekov S.T. Psychometric properties of the Bulgarian version of the Quality of Life in Epilepsy Inventory (QOLIE-31). Epilepsy Behav [Internet] 2013;28(2):203–10. https://doi.org/10.1016/j.yebeh.2013.05.014.
[33] Andreychik MR. Feeling your joy helps me to bear feeling your pain: Examining associations between empathy for others' positive versus negative emotions and burnout. Pers Individ Dif [Internet]. 2019;137(August 2018):147–56. Available from: https://doi.org/10.1016/j.paid.2018.08.028.
[34] Bloore RA, Jose PE, Roseman IJ. General emotion regulation measure (GERM): Individual differences in motives of trying to experience and trying to avoid experiencing positive and negative emotions. Pers Individ Dif [Internet]. 2020;166(March):110174. Available from: https://doi.org/10.1016/j.paid.2020.110174.
[35] Johnson S.L, Elliott M.V, Carver C.S. Impulsive Responses to Positive and Negative Emotions: Parallel Neurocognitive Correlates and Their Implications. Biol Psychiatry [Internet] 2020;87(4):338–49. https://doi.org/10.1016/j.biopsych.2019.08.018. Available from:
[36] Martinović Ž, Milovanović M, Tošković O, Jovanović M, Buder N, Simonović P, et al. Psychometric evaluation of the Serbian version of the Quality of Life in Epilepsy Inventory-31 (QOLIE-31). Available from. Seizure [Internet] 2010;19(8):517–24. https://linkinghub.elsevier.com/retrieve/pii/S1059131110001615.

[37] Mohammadi N, Kian S, Davoudi F, Nia S.M.A.A, Nojomi M. Psychometric evaluation of the Persian version of the quality of life in epilepsy inventory-31. Available from. Iran J Neurol [Internet] 2013;12(4):144–8. http://www.ncbi.nlm.nih.gov/pubmed/24250924%0Ahttp://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC3829300.

[38] Scévola L, Teitelbaum J, Oddo S, Centurión E, Loidl C.F, Kochen S, et al. Psychiatric disorders in patients with psychogenic nonepileptic seizures and drug-resistant epilepsy: A study of an Argentine population. Available from. Epilepsy Behav [Internet] 2013;29(1):155–60. https://linkinghub.elsevier.com/retrieve/pii/S1525505013003351.

[39] Scévola L, Sarudiansky M, Lanzillotti A, Oddo S, Kochen S, D'Alessio L. To what extent does depression influence quality of life of people with pharmacoresistant epilepsy in Argentina? Epilepsy Behav [Internet]. 2017;69:133–8. Available from: http://dx.doi.org/10.1016/j.yebeh.2017.01.007.

[40] Rodríguez C.A, Kubis M.M, Arteaga C.B.T, Fustes O.J.H. Psychiatric Comorbidities in Epilepsy. Available from. J Epilepsy Res [Internet] 2022;12(1):21–6. http://www.j-epilepsy.org/journal/view.php?doi=10.14581/jer.22004.

[41] Gaitatzis A, Trimble M.R, Sander J.W. The psychiatric comorbidity of epilepsy. Available from. Acta Neurol Scand [Internet] 2004;110(4):207–20. https://onlinelibrary.wiley.com/doi/10.1111/j.1600-0404.2004.00324.x.

[42] Boylan L.S, Flint L.A, Labovitz D.L, Jackson S.C, Starner K, Devinsky O. Depression but not seizure frequency predicts quality of life in treatment-resistant epilepsy. Available from. Neurology [Internet] 2004;62(2):258–61. https://www.neurology.org/lookup/doi/10.1212/01.WNL.0000103282.62353.85.

[43] Kaptein A.A, Yamaoka K, Snoei L, van der Kloot W.A, Inoue K, Tabei T, et al. Illness Perceptions and Quality of Life in Japanese and Dutch Women with Breast Cancer. Available from. J Psychosoc Oncol [Internet] 2013;31(1):83–102. http://www.tandfonline.com/doi/abs/10.1080/07347332.2012.741092.

[44] Kaptein A.A, Yamaoka K, Snoei L, Kobayashi K, Uchida Y, van der Kloot W.A, et al. Illness perceptions and quality of life in Japanese and Dutch patients with non-small-cell lung cancer. Available from. Lung Cancer [Internet] 2011;72(3):384–90. https://linkinghub.elsevier.com/retrieve/pii/S0169500210004411.

[45] Timmers L, Thong M, Dekker F.W, Boeschoten E.W, Heijmans M, Rijken M, et al. Illness perceptions in dialysis patients and their association with quality of life. Available from. Psychol Health [Internet] 2008;23(6):679–90. http://www.tandfonline.com/doi/abs/10.1080/14768320701246535.

[46] Griva K, Jayasena D, Davenport A, Harrison M, Newman S.P. Illness and treatment cognitions and health related quality of life in end stage renal disease. Available from. Br J Health Psychol [Internet] 2009;14(1):17–34. http://doi.wiley.com/10.1348/135910708X292355.

[47] Covic A, Seica A, Gusbeth-Tatomir P, Gavrilovici O, Goldsmith D.J.A. Illness representations and quality of life scores in haemodialysis patients. Available from. Nephrol Dial Transplant [Internet] 2004;19(8):2078–83. https://academic.oup.com/ndt/article-lookup/doi/10.1093/ndt/gfh254.

[48] Chow P.-C. Quality of life, psychological resilience, personality traits and illness perception in grown-up congenital heart patients in Hong Kong. Available from. Int J Cardiol Congenit Hear Dis [Internet] 2021;6:100279. https://linkinghub.elsevier.com/retrieve/pii/S2666668521002032.

[49] Shallcross A.J, Becker D.A, Singh A, Friedman D, Montesdeoca J, French J, et al. Illness perceptions mediate the relationship between depression and quality of life in patients with epilepsy. Epilepsia 2015;56(11):e186–90.

[50] Kerr C, Nixon A, Angalakuditi M. The impact of epilepsy on children and adult patients' lives: Development of a conceptual model from qualitative literature. Seizure [Internet] 2011;20(10):764–74. https://doi.org/10.1016/j.seizure.2011.07.007.

[51] Sarudiansky M, Korman G.P, Scévola L, Oddo S, Kochen S, D'Alessio L. A life with seizures: Argentine patients' perspectives about the impact of drug-resistant epilepsy on their lives. Available from. Seizure [Internet] 2018;63(October):52–61. https://linkinghub.elsevier.com/retrieve/pii/S105913111830534X.

[52] Ghanean H, Jacobsson L, Nojomy M. Self-perception of stigma in persons with epilepsy in Tehran. Available from. Iran Epilepsy Behav [Internet] 2013;28(2):163–7. https://linkinghub.elsevier.com/retrieve/pii/S1525505013001935.

[53] Haritomeni P, Aikaterini T, Theofanis V, Elizabeth D, Ioannis H, Konstantinos V, et al. The Greek Version of the Quality of Life in Epilepsy Inventory (QOLIE-31). Available from. Qual Life Res [Internet] 2006;15(5):833–9. http://link.springer.com/10.1007/s11136-005-5149-9.

[54] Cramer J.A, Mueller K, Borgs S. Testing a new QOLIE-31-P Total score algorithm using data from brivaracetam Phase III studies [Internet]. American Epilepsy Society Annual. Available from: Meeting Abstracts 2016. https://cms.aesnet.org/abstractslisting/testing-a-new-qolie-31-p-total-score-algorithm-using-data-from-brivaracetam-phase-iii-studies.