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Validity and reliability of the Italian version of the *Quality-of-Life in Epilepsy Inventory* (QOLIE-31)

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Summary

Purpose : To develop an Italian adaptation of the shortened version of the *Quality-of-Life in Epilepsy Inventory* (QOLIE-31).
Methods : The study population comprised 503 consecutive ambulatory patients with epilepsy from 44 centers. Internal validity was tested by factor analysis, to detect similarities to and differences from the original version, and by multitrait/multi-item analysis, to assess item convergent and discriminant validity. External validity testing included correlation to the SF-36 Inventory, to check the properties of the epilepsy-specific dimensions. Validity testing was completed by analysis of variance (ANOVA) of QOLIE-31 dimension scores against demographic and clinical variables, including age, sex, seizure frequency and number of drugs.
Results : The domains showing the highest internal consistency and the best discriminant validity were *Medication effect*, and *Seizure worry. Social functioning* had the lower discriminant validity. With reference to the SF-36 scores, the study patients were slightly but constantly below the population values, mostly for *General health* and *Role physical* domains. All QOLIE-31 dimensions were sensitive to almost any demographic and clinical variable, except for *Medication effects* (sensitive to number of drugs) and *Energy—fatigue* (sensitive to age).
Conclusions : Except for *Social functioning*, the psychometric properties of the Italian adaptation of the QOLIE-31 Inventory are fairly good and similar to the American version and the Spanish translation. *Social functioning* scale suffers shortcomings because of life constraints caused by epilepsy (with missing values for regular job and driving license).

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Introduction

In recent years, health care assessment in epilepsy has expanded to include the viewpoints of the patients and their caretakers and to introduce the concept of health-related quality-of-life (HRQOL) as a measure of outcome in research and in clinical practice.[1] Several approaches have been adopted in questionnaires to assess HRQOL in epilepsy.

A first example is the model-driven approach suggested by researchers from Liverpool University. Their model includes epilepsy concerns, each analysed through batteries of validated tests designed for conditions other than epilepsy.[2,3] A second approach involves newer epilepsy-specific instruments. This is the strategy used, for instance, for the *Social Effect Scale*,[4,5] the *Washington Psychosocial Seizure Inventory* (WSPI),[6,7] and the *Side Effects and Life Satisfaction* (SEALS).[8] Using this same approach the Liverpool researchers later developed specific scales within the same original model, such as the *Impact of Epilepsy Scale*, the *Mastery Scale* and others.[9,10]

A third approach uses a generic core, such as the Short Form 36 (SF-36),[11,12] supplemented by items specific to epilepsy. This led to a revised version of the Katz Adjustment Scale,[13] followed by the ESI-55 for surgical patients,[14] and the *Quality-of-Life in Epilepsy Inventory* (QOLIE-89)[15] with its shortened version QOLIE-31.[16] The QOLIE-31 was designed to serve as a brief form to assess epilepsy-specific and some general HRQOL issues. Cross-cultural translation of the QOLIE-31 has been completed[16] and there is now a Spanish and a German version.[17,18] We set out to develop an Italian version of the QOLIE-31 Inventory.

Methods

The QOLIE-31 includes 31 items clustered in seven multi-item scales centered on the following domains: *Overall quality of life*, *Emotional well-being*, *Energy—fatigue*, *Cognitive functioning*, *Medication effects*, *Seizure worry*, and *Social functioning*. A scoring system is available for each item (from 0 to 3 or from 0 to 6) and calculated for each scale (from 0, the worst HRQOL, to 100, the best). Scores are obtained by dividing the sum of the valid item scores by the number of items with valid responses in each scale. An overall score is also produced by summing the scores of each scale weighted by coefficients obtained by regressing the summary score of the QOLIE-89 on the seven QOLIE-31 sub-scales taken as predictors.[19]

The QOLIE-31 has now been translated and culturally adapted in nine languages (including Italian) by the MAPI Research Institute (Lyon, France).[20] One of us (M.N.) followed the Italian translation and adaptation of the inventory. The method of adaptation aimed at obtaining the best conceptual equivalence, following the traditional steps of double translation, back-translation and field testing on 10 patients.

Study plan

The psychometric validation of the QOLIE-31 involved 503 consecutive ambulatory adults with epilepsy from 44 referral centers. A patient was considered eligible if she/he was able to understand and complete the questionnaire. The study plan included descriptive statistics of the QOLIE-31 scales and reliability assessment (Cronbach's alpha). A general distinction can be made between internal and external validity procedures. Internal validity, based on scaling properties and consistency of the sub-scales, was tested through: (a) exploratory factor analysis to detect similarities to and differences from the original experimental version of the QOLIE-31 Inventory; (b) multitrait/multi-item analysis (MAP-R)[21] to assess item convergent (how the items belong to the prescribed scale) and discriminant validity (probability of the item belonging to scales other than those prescribed). External validity testing included: a) correlation to the SF-36 Inventory, to check the properties of the epilepsy-specific dimensions, such as *Seizure worry* and *Medication effect*. Correlations with the SF-36 dimensions were assumed as divergent for $r < 0.5$, convergent for $r = 0.5—0.7$, overlapping for $r > 0.7$; (b) analysis of variance (ANOVA) of each of the QOLIE-31 sub-scales against demographic and clinical variables: sex, age, type of seizures, frequency of seizures, disease duration from diagnosis and number of antiepileptic drugs (AEDs). Frequency was adjusted for severity of seizures by ranking patients in three levels of frequency (low, medium, high), as suggested by Cramer et al.[16] Thus, for example, 5—12 generalized tonic—clonic seizures per year correspond to 101—200 simple partial, absence or myoclonic seizures and are classified as ''high'' frequency: 2—4 tonic—clonic seizures correspond to 21—100 simple partial/absence myoclonic seizures and are classified as ''medium'' frequency; 1 tonic—clonic seizure corresponds to 1—20 simple-partial, absence/myoclonic seizures and is classified as ''low'' frequency.

Patients were ranked as having epilepsy diagnosed in the last 5 years against all the others having epilepsy diagnosed earlier. When the span between diagnosis and test was reduced from 5 to 2 years, the results were no different.

Construct validity rationale was assessed under the following hypotheses: (1) *Seizure worry* was expected to be significantly related to the type/frequency of seizures and to be worse in patients with newly-diagnosed epilepsy; (2) *Cognitive functioning* was expected to fall significantly with age, frequency of seizures and number of AEDs; (3) *Medications effect* was expected to rise significantly with the number of AEDs; (4) *Emotional well-being* was expected to be significantly related to sex; (5) *Social functioning* was expected to be sensitive to seizure frequency and number of AEDs; (6) *QOLIE-31 total score* was expected to be sensitive to the most important clinical variables, such as seizure frequency and AEDs.

Results

Sample characteristics

The sample comprised 258 women (53%) and 226 men (47%) aged 14—80 years (mean 37 years); 312 (62%) had basic education (8 years), 189 (38%) were formally employed, and 46 (9%) had some disability, mostly caused by epilepsy. Partial seizures (simple and/or complex) were present in 160 cases (32%), followed by generalized tonic—clonic seizures (95, 19%), secondarily generalized seizures (85, 17%), absence seizures (15, 3%), and other seizure types (15, 3%). As many as 110 patients (22%) presented two or more seizure types; 15 (3%) had unclassified seizures. A total of 245 patients (49%) received monotherapy, 176 (35%) were treated with two AEDs, and 79 (16%) with three or more. Seizure-free patients were 55 (11%). Three quarters (375 cases, 75%) had 1—10 seizures in the preceding month, 45 (9%) 11—30, and 25 (5%) more than 30.

Descriptive statistics and reliability

For each item, missing values ranged from 1 to 13 (mean 6, corresponding to an average of 1.2%), except for items 20 (*driving)* and 27 (*working*), included in the *Social functioning* scale, for which there were 211 and 168 missing values (41.9 and 33.4% of responses, respectively). As seen above, the procedure suggested in the Scoring Manual[19] was followed. The problem of missing values was overcome by dividing the total sum of valid item scores (transformed on a 0—100 scale) for each patient by the number of items with valid responses in the scale. The replacement method suggested for the SF-36 (missing values = mean of the items with valid responses in the scale)[22] was also used to deal with the *Social functioning* scale.

Descriptive statistics of the QOLIE-31 scores are presented in Table 1. Mean scores ranged from 54 to 71 with large standard deviations. Internal consistency and reliability for almost all domains was acceptable, Cronbach's alpha ranging from 0.884 to 0.741. Distribution was skewed for all the scales, with a tendency for the responses to concentrate towards the highest scores. This tendency was maximal for *Medication effects* and *Social functioning*, with a ceiling effect in respectively 12.9 and 18.7% of the responses.

Internal validity

As in RAND's reference study,[19] seven factors were identified from the original main component analysis, by retaining those with eigenvalues greater than 1 (see Varimax rotated matrix in the Appendix A). All items belonging to the QOLIE-31 scales highly loaded one sole factor (factor loadings greater than 0.5), except for *Emotional well-being* items which tended to highly load a factor also loaded by some of

Table 1 QOLIE-31 scores (summary statistics).

QOLIE-31 sub-scale	No. of items	Mean	S.D.	Floor (%)	Ceiling (%)	Inter-item correlation (Pearson's *r*)			Alpha
						Mean	Max	Min	
Seizure worry	5	53.882	26.584	2.2	4.2	0.522	0.677	0.345	0.842
Overall quality of life	2	62.913	19.454	0.6	2.4	0.632	0.632	0.632	0.774
Emotional well-being	5	63.860	19.488	0.4	1.4	0.515	0.712	0.275	0.839
Energy—fatigue	4	57.166	20.320	0.4	1.4	0.513	0.787	0.376	0.808
Cognitive functioning	6	65.733	24.189	0.2	5.8	0.571	0.780	0.398	0.884
Medication effects	3	59.837	28.537	4	12.9	0.611	0.812	0.485	0.826
Social functioning	5	70.561	24.560	0.6	18.7	0.385	0.725	0.142	0.741 [a]
Overall QOLIE-31	30	63.956	18.274	0.2	0.2				0.876

S.D.: standard deviation.
[a] Based on 238 out of 503 cases.

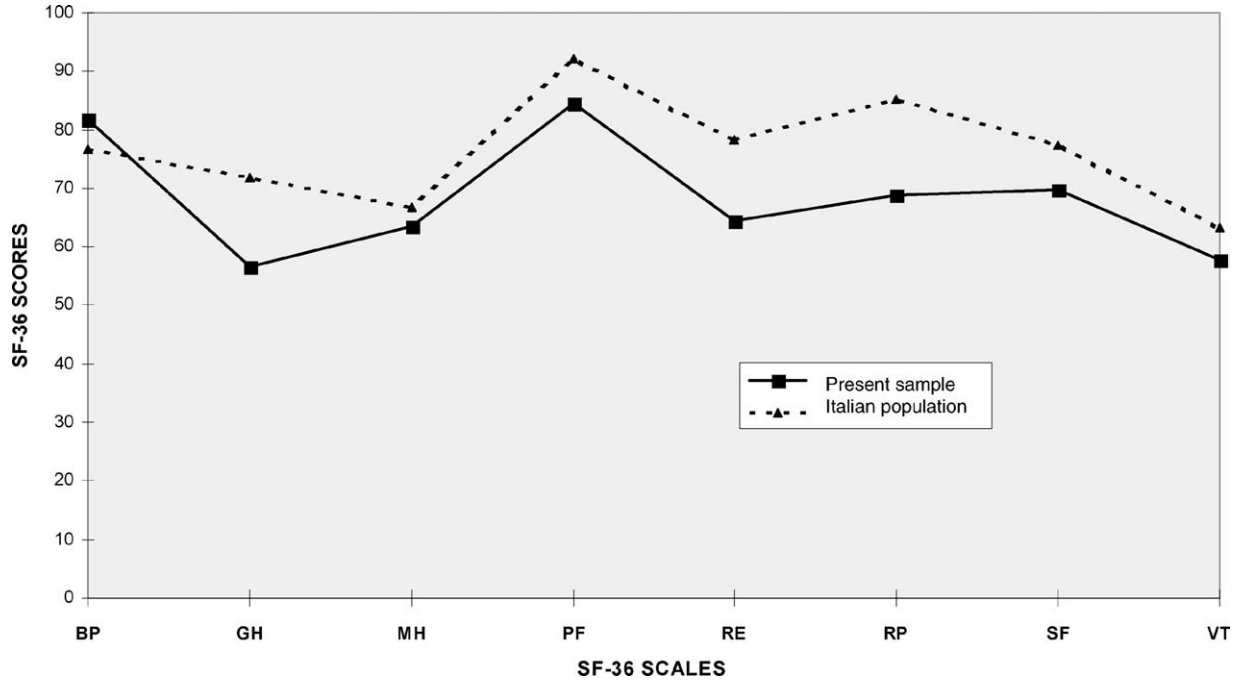

Figure 1 SF36 scores in the present sample and in the Italian population (median age). BP: Bodily pain; GH: General health; MH: Mental health; PF: Physical functioning; RE: Role emotional; RP: Role physical; SF: Social functioning; VT: Vitality.

the *Energy—fatigue* items, and vice-versa. Items on the *Social functioning* scale loaded two factors on their own. The domains showing the highest mean inter-item correlations were *Overall QOL*, *Medication effect*, and *Seizure worry* (Table 1). By contrast, the five items in the *Social functioning* scale showed a low mean inter-item correlation (r = 0.385). These results are confirmed by the MAP-R test which indicates full discriminant validity (100%) for *Seizure worry*, *Cognitive functioning* and *Medication effects* scales, intermediate with *Emotional well-being* and *Energy—fatigue* scales (93 and 87%), and lower with the *Overall QOL* and *Social functioning* scales (83%).

External validity

Comparing the SF-36 scores of the study patients with the Italian population,[22] the two samples had the same *Bodily pain* score but differed on the *General health* and *Role physical* scales. For all the other indices, the patients were slightly but constantly below the corresponding population values (Fig. 1, Table 2). By correlating SF-36 and QOLIE dimensions in the study population and considering correlations greater than 0.7 (overlapping), the QOLIE-31 *Overall QOL* showed a close correlation with SF-36 *General health* and *vitality*; *Energy—fatigue* with SF-36 *Vitality*; and *Emotional well-*

Table 2 Correlations between QOLIE-31 and SF-36 sub-scales.

SF-36/QOLIE-31	SW	OQL	EWB	E—F	CO	ME	SOF	QOLIE
BP	0.255	0.355	0.348	0.334	0.289	0.152	0.301	0.376
GH	0.540	0.755	0.617	0.688	0.535	0.367	0.643	0.751
MH	0.475	0.676	0.865	0.709	0.542	0.377	0.575	0.757
PF	0.266	0.440	0.369	0.424	0.537	0.143	0.542	0.560
RE	0.353	0.542	0.524	0.547	0.537	0.272	0.527	0.628
RP	0.391	0.549	0.485	0.514	0.477	0.235	0.557	0.608
SF	0.477	0.652	0.622	0.596	0.609	0.384	0.676	0.753
VT	0.479	0.718	0.731	0.903	0.552	0.350	0.602	0.779

BP: Bodily pain; GH: General health; MH: Mental health; PF: Physical functioning; RE: Role emotional; RP: Role physical; SF: Social functioning; VT: Vitality; SW: Seizure worry; OQL: Overall quality of life; EWB: Emotional well-being; E—F, Energy—fatigue; CO: Cognitive functioning; ME: Medication effects; SOF: Social functioning; QOLIE: Overall QOLIE.

Table 3 Correlations between QOLIE-31 scales and external variables.

Sex	QOLIE	SOF	ME	CO	E—F	EWB***	OQL	SW***
Age	QOLIE***	SOF***	ME	CO***	E—F***	EWB***	OQL***	SW
Duration of disease	QOLIE***	SOF***	ME	CO***	E—F	EWB***	OQL***	SW***
Seizures types	QOLIE	SOF	ME	CO	E—F	EW	OQL	SW***
Seizure frequency	QOLIE***	SOF***	ME	CO***	E—F	EWB***	OQL***	SW***
No. of drugs	QOLIE***	SOF***	ME***	CO***	E—F	EWB	OQL***	SW

QOLIE: Overall QOLIE; SOF: Social functioning; ME: Medication effects; CO: Cognitive functioning; E—F: Energy—fatigue; EWB: Emotional well-being; OQL: Overall quality of life; SW: Seizure worry.
*** $p \leq 0.005$ (one-way ANOVA).

being with SF-36 *Mental health* (the last three subscales containing identical items). By contrast, correlations with all the SF-36 dimensions were divergent ($r < 0.5$) for *Medications effect* and *Seizure worry* (the latter only correlated beyond the threshold with SF-36 *General health*). Correlations were also divergent for the QOLIE-31 dimensions and SF-36 *Bodily pain*. Convergence with all the SF-36 dimensions ($r = 0.5$—0.7) except *Bodily pain* was shown by the QOLIE-31 scales *Social functioning* and *Cognition*.

Applying one-way ANOVA to the demographic and clinical variables (Table 3) and considering only highly significant interactions ($p < 0.005$), the main results were the following: *Medications effect* was sensitive to number of drugs, and *Energy—fatigue* only to age; seizure frequency and number of drugs affected all QOLIE-31 dimensions except *Medications effect* (the former) and *Energy—fatigue* (both); *Emotional well-being* was sensitive to sex, age, disease duration and seizure frequency; *Cognition* was sensitive to age, seizure frequency, disease duration and number of drugs; seizure type seemed only to affect *Seizure worry*. This does not follow the expected order as to clinical severity since the mean score for primary tonic—clonic seizures was 56.253 compared to 54.092 for complex partial seizures and 49.553 for secondarily generalized seizures.

Discussion and conclusion

It would appear that the psychometric properties of the Italian adaptation of the QOLIE-31 Inventory are good, and similar to those of the American version[14] and its Spanish translation.[15] The only real problem is in the dimension *Social functioning*. Items like ''driving'' and ''working'' had a high rate of missing values, possibly reflecting constraints caused by epilepsy. We used two strategies for missing values: the one recommended by the QOLIE-31 authors and the SF-36 procedure. When there are only a few missing values, both give similar results, as in most of the QOLIE-31 scales. Differences can be substantial, however, when there are several missing values. This is the case with the *Social functioning* scale where, adopting the Scoring Manual solution, some scaling psychometrics, such as alpha, item-scale and inter-item correlations are calculated on a limited number of patients, mostly those with a regular job and a driving license (208 out of 503 respondents). As a result alpha is 0.741. Using the SF-36 procedure and replacing missing values with the mean of the non-missing values of the items in the scale, alpha is 0.842. Although it still suffers from these problems, the first solution is more reasonable, because patients are questioned only about aspects that are an actual part of their life, excluding judgments on driving and working if not applicable. The second solution artificially increases the consistency and levels of scores.

With both solutions the *Social functioning* scale suffers other shortcomings since the ceiling effect is 18.7% with the first and 15.1% with the second strategy. On the one hand, driving and working are important aspects of social life; on the other, the points made above would undermine consistency because these items apply only to a limited sub-group of patients. This was the point raised by patients participating in two focus groups in Italy prior to this study. As a compromise it was suggested we should add the item ''not applicable'' in the ''driving'' and ''working'' scales in the Italian version of the QOLIE-31. However, though it makes it easier to complete the questionnaire, this does not solve the problem.

All other scales show good internal consistency, with a Cronbach's alpha greater than 0.8, except for *Overall QOL*. This can probably be explained by the small number of items (two) in the scale. With reference to *Social functioning*, four of the five items spread over three factors in the Varimax rotated matrix (see Appendix A) probably because of the problems caused by driving and working, while items belonging to the other scales agree with the findings with the same instrument in the USA.

Correlations with the SF-36 show that the epilepsy-specific scales *Medications effect* and *Seizure worry* are weakly related to general aspects of HRQOL. As to the original sources of the QOLIE-31 items, the scales

from the SF-36 Inventory (*Emotional well-being* and *Energy—fatigue*) show an almost normal distribution while the remaining scales are skewed, with striking ceiling effects. This is particularly true for *Medication effects* (ceiling effect 13%) and *Social functioning* (19%) and, to a lesser extent, for *Cognitive functioning* (6%) and *Seizure worry* (4%).

Most of the construct validity hypotheses were met, as shown in Table 3. As expected, *Seizure worry* was significantly related to *Seizure frequency*. *Cognitive functioning* was significantly related to the deterioration due to age, frequency of seizures and AEDs, while *Medication effects* increased with the number of drugs. *Emotional well-being* was related to sex and decreased significantly with age. Finally, the overall QOLIE-31 score was sensitive to seizure frequency and number of drugs, and was lower in older patients.

The construct validity hypotheses that were not met included *Type of seizures*, which were significantly related to *Seizure worry*, but the highest scores did not correspond to the clinical severity of seizures. In addition, *Duration of disease* did not seem to follow what is reported about newly diagnosed seizures.[23] Patients with epilepsy diagnosed during the last 5 years did not have different scores from those with longer-dating disease on any of the QOLIE-31 dimensions. These apparently contrasting findings can be interpreted by assuming that HRQOL in patients with epilepsy is not significantly affected by seizure severity and disease duration. Cultural and social factors may play a role, making comparisons across countries difficult for these specific aspects.

The correlation between several demographic and clinical variables and *Social functioning*, *Cognitive functioning* and *Overall QOL* show that the QOLIE-31 includes aspects that are suitable for a comprehensive assessment and evaluation of patients with epilepsy.

In conclusion, even with some limitations, the Italian version of the QOLIE-31 Inventory shows fairly good reliability, internal and external validity, supporting its use as a specific measure of the HRQOL in epilepsy in Italy.

Appendix A. Varimax rotated matrix

	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7
SW1	0.15162	0.22128	0.32136	0.62122	0.09081	0.35584	−0.03959
SW2	0.19662	0.19565	0.12637	0.78034	0.09517	0.23017	0.00653
SW3	0.18370	0.16513	0.11391	0.69049	0.08812	0.10391	0.07003
SW4	0.17800	0.18280	0.10515	0.78087	0.14026	0.04798	0.03020
SW5	0.19485	0.05624	−0.02746	0.64532	0.26040	−0.13413	0.37805
OQL1	0.61171	0.22768	0.17733	0.10133	0.08074	0.31454	0.13335
OQL2	0.63431	0.29574	0.18308	0.20948	0.15296	0.26204	0.10883
EWB1	0.13345	0.10692	0.76392	0.16716	0.06649	−0.08420	0.16517
EWB2	0.34457	0.24656	0.69648	0.07402	0.06840	0.16418	0.11479
EWB3	0.71269	0.11899	0.29843	0.21108	0.15423	−0.09181	0.14995
EWB4	0.40728	0.17432	0.66377	0.09322	0.06199	0.18466	0.07586
EWB5	0.82057	0.08264	0.17017	0.15409	0.05119	0.10153	0.04054
E—F1	0.81508	0.11760	0.20795	0.18843	0.16248	0.11689	0.04466
E—F2	0.81962	0.11420	0.21779	0.16883	0.12376	0.06650	0.04382
E—F3	0.14174	0.24664	0.73211	0.05400	0.11138	0.22741	−0.00160
E—F4	0.27858	0.20183	0.65502	0.15320	0.05292	0.09445	−0.05631
CO1	0.16523	0.57350	0.31198	0.13206	0.10509	0.40358	0.02223
CO2	0.20926	0.79492	0.11219	0.15509	0.06641	0.00416	0.10812
CO3	0.13737	0.82771	0.23725	0.08939	0.07053	0.06887	0.04228
CO4	0.09076	0.76435	0.19503	0.18722	0.07693	0.22644	−0.00221
CO5	0.13398	0.76474	0.18459	0.25303	0.11427	0.21171	0.05356
CO6	0.14043	0.55482	0.09394	0.14852	0.35780	−0.15048	0.43828
ME1	0.17109	0.07215	0.15903	0.24309	0.69383	0.00498	−0.19979
ME2	0.10413	0.08116	0.03868	0.10792	0.87666	0.10082	0.19134
ME3	0.11680	0.13814	0.06894	0.09479	0.85307	0.06084	0.20952
SOF1	0.31899	0.35072	0.32311	0.10095	0.16701	0.60088	0.03364
SOF2	0.13684	0.32270	0.19511	0.29384	0.16716	0.62371	0.00290
SOF3	0.18330	0.03273	0.03313	0.14255	−0.04151	0.59327	(0.42886)
SOF4	0.12288	0.09246	0.14685	0.07619	0.17846	0.16082	0.80258
SOF5	0.26050	0.25762	0.09051	0.15783	0.50284	0.16987	(0.43662)

SW: Seizure worry; OQL: Overall quality of life; EWB: Emotional well-being; E—F: Energy—fatigue; CO: Cognitive functioning; ME: Medication effects; SOF: Social functioning.

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