

ARTÍCULO II: VALIDACIÓN PSICOMÉTRICA DEL INSTRUMENTO

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Resumen

Propósito. Una consecuencia común y frecuente de un daño cerebral adquirido es la disminución en la calidad de vida de las personas afectadas. Debido a que la mayoría de los instrumentos de calidad de vida existentes evalúan las dimensiones relacionadas con la salud, se justifican nuevos instrumentos que permitan la evaluación de la calidad de vida desde una perspectiva integral que tenga en cuenta el contexto y los factores personales de la persona. Por lo tanto, el propósito de este estudio es desarrollar y validar un instrumento con estas características. **Método.** La Escala CAVIDACE es un nuevo instrumento específico de 64 ítems para evaluar la calidad de vida en personas con daño cerebral adquirido basado en una perspectiva de tercera persona. La muestra de validación comprendió 421 adultos con daño cerebral adquirido, con edades comprendidas entre 17 y 90 años ($M = 53.12$; $DT = 14.87$). La escala fue completada por 97 profesionales y 58 familiares. La evidencia de validez, basada en la estructura interna de la escala, se proporcionó a través de análisis factoriales confirmatorios. La fiabilidad se analizó en términos de consistencia interna y fiabilidad entre evaluadores. **Resultados.** Los resultados apoyaron la estructura interna de la escala, basada en el marco teórico y de evaluación en el que la calidad de vida se compone de ocho dimensiones de primer orden interrelacionados ($CFI = .890$, $RMSEA = .065$, $SRMR = .071$). La consistencia interna fue buena o excelente para las ocho dimensiones (alfa ordinal varió de .81 a .93). La fiabilidad entre evaluadores fue muy alta (.97). **Conclusiones.** La Escala CAVIDACE es un instrumento específico con excelentes propiedades psicométricas que es útil para la evaluación de la calidad de vida en personas con daño cerebral adquirido, tanto en la práctica clínica como con fines de investigación.

Palabras clave. Calidad de vida, daño cerebral adquirido, propiedades psicométricas, prácticas basadas en la evidencia, medida de resultado, escala CAVIDACE.



A new scale for measuring quality of life in acquired brain injury

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Abstract

Purpose A common and frequent consequence of an acquired brain injury (ABI) is the diminished quality of life (QoL) of affected people. Because the majority of existing QoL instruments assess health-related domains, new instruments that allow for the evaluation of the QoL from an integral perspective that considers the context and personal factors of the individual are warranted. Hence, the purpose of this study is to develop and validate an instrument with these characteristics.

Methods The CAVIDACE scale is a new 64-item specific instrument to assess QoL in people with ABI based on a third-person perspective. The validation sample comprises 421 adults with ABI, with ages ranging from 17 to 90 years ($M=53.12$; $SD=14.87$). The scale was completed by 97 professionals and 58 family members. Validity evidence based on the internal structure of the scale was provided through confirmatory factor analyses. Reliability was analyzed in terms of internal consistency and inter-rater reliability.

Results The results supported the internal structure of the scale, based on the theoretical and assessment framework in which QoL is composed of eight intercorrelated first-order domains ($CFI=0.890$, $RMSEA=0.065$, $SRMR=0.071$). The internal consistency was good or excellent for the eight domains (ordinal alpha ranging from 0.77 to 0.93). The inter-rater reliability was very high (0.97).

Conclusions The CAVIDACE scale is found to be a specific instrument with excellent psychometric properties that is helpful for the assessment of QoL in people with ABI, both in clinical practice and for research purposes.

Keywords Quality of life · Acquired brain injury · Psychometric properties · Evidence-based practices · Outcome measure · CAVIDACE scale

Introduction

After an acquired brain injury (ABI), people may experience a wide range of different impairments (e.g., functional, cognitive, emotional, and social) as a consequence of the injury [1]. These changes may affect people's life differently, depending on the cause (i.e., etiology: traumatic brain injury, stroke, tumor, anoxia, or infection), the degree of severity, and the individual's personal characteristics, among others. However, a common and frequent consequence after an ABI is the negative impact that these alterations have on the quality of life (QoL) of injured people, which has been reported to be significantly diminished [2–4].

The increased rates of ABI over the last years and the situations of disability and dependency that often remain after recovery have made many professionals and researchers to be interested in the personal outcomes of QoL after an ABI [5]. One of the reasons is that considering the personal

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outcomes in QoL allows professionals to obtain a personal measure to evaluate the efficacy and efficiency of the strategies planned and the interventions conducted. Moreover, planning an intervention based on personal goals and preferences, and appropriate models, makes interventions meaningful for the individual, ensuring the compliance with the rights of persons with disabilities [6]. These aspects highlight the importance of studying QoL in the ABI population and, for this purpose, the existence of adequate and specific assessment scale is needed.

Currently, the QoL approach most commonly used in people with ABI is mainly based on the measurement of health-related personal outcomes (i.e., health-related quality of life -HRQoL). There are several instruments available to assess HRQoL in ABI, both generic and disease-specific. Among them, the Medical Outcomes 36-Item Short Form Health Survey (SF-36) [7] is the most commonly used generic tool [8], while the European Brain Injury Questionnaire (EBIQ) [9] and the Quality of Life after Brain Injury (QOLIBRI) scale [10–12] have been developed, validated, and adapted specifically for ABI and are widely used in research and professional practice [13]. However, the QoL outcomes obtained from these assessment tools are circumscribed to a few QoL-related aspects that offer a limited outcome-profile by disregarding or omitting crucial areas of people's welfare. In this way, EBIQ focuses on three aspects: cognitive, emotional, and social difficulties; while QOLIBRI is based on a six-domain model in which items refer to "satisfaction" aspects (satisfaction with cognition, self, life and daily autonomy, and social relationships) and "bothered" aspects (feeling bothered by emotions and physical problems). Other crucial aspects such as social inclusion, material well-being, rights, personal development are missing or ignored when QoL of this population is assessed. Moreover, the existing HRQoL instruments are self-reported and reflects people with ABI perspective but it is important to note that their responses may be influenced by cognitive deficits, including an altered awareness, that may lead to unreliable assessment [3].

Hence, there is a need for more comprehensive assessments of QoL that also includes contextual factors [14] and reflects a psychosocial approach that goes beyond health-related aspects. Considering all the important areas in people's lives may lead to improve professional practices aimed to enhance people's quality of life if they are focused on contextual aspects that might be modified. In this sense, developing and validating new instruments focused on the context and based on comprehensive QoL models become a priority and an urgent need. Aimed at this target population and at filling this gap, the CAVIDACE scale ('calidad de vida en daño cerebral' in Spanish; 'quality of life in brain injury' in English) was developed as a specific tool to assess the QoL of adults with ABI from a comprehensive perspective in

which QoL is understood not only as a health condition but also as a product of the interaction between the person and the context in which it is involved.

The CAVIDACE scale is developed on the basis of the QoL model proposed by Schalock and Verdugo [15]. In this model, QoL is defined as a multidimensional phenomenon composed of eight core domains of personal well-being: emotional well-being (EW), physical well-being (PW), material well-being (MW), self-determination (SD), interpersonal relationships (IR), social inclusion (SI), personal development (PD), and rights (RI). These domains are assessed through domain-referenced indicators and influenced by both personal characteristics and environmental factors. The core domains are the same for all people, although they may vary individually in relative value and importance. The concept encompasses objective and subjective components, and the assessment of QoL domains is based on culturally sensitive indicators [16–26].

This model, backed by many years of research in both the national and international scope, has been widely used in the field of disability, mainly in the intellectual and developmental disabilities [23, 24]. In recent years, it has been expanded and generalized to other diagnostic groups that are at risk of social exclusion and other human service recipients, such as those with mental health problems, substance dependence, and physical and sensory disabilities, the elderly [18], and individuals with ABI [27]. These results reinforce the fact that the core domains of QoL can also be generalized to other vulnerable groups [28]. The operationalization of the concept in ABIs allows organizations and centers that offer services to individuals with ABI to evaluate personal outcomes and thus to improve the delivery of services and the planning of interventions based on their specific needs [29–33].

To develop the field-test version of the CAVIDACE scale, a previous study was conducted to obtain a wide pool of adequate items to assess QoL in this population. The development of the scale was based on an extensive review of the scientific literature, a group discussion with professionals who provide services to people with ABI, and a Delphi study—a methodology that involved 14 experts in ABI to provide content validity for a pool of 120 items that made up the field-test version of the CAVIDACE scale, with very high agreement between the judges ($M=0.82$). All details about the development of the scale and these methods are exhaustively detailed in Authors et al. [27].

Once the field-test version of CAVIDACE scale was developed, the next step was aimed at validating the instrument. So, the objective of this paper is to describe the validation process, including the procedure of selecting the most relevant and significant items, as well as the analysis of the psychometric properties of the scores obtained in a heterogeneous sample of people with ABI (i.e., validity and

reliability). Instruments with adequate evidence of reliability and validity are cornerstones of clinical research because they are necessary for the results to be accurately applied and interpreted. In the assessment of QoL, it is particularly important to evaluate the methodological quality of studies in which the measurement properties of the instruments are assessed according to specific standards. Thus, we applied the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist [34], which is widely used for this purpose [35–37].

Method

Participants

The field-test version of the CAVIDACE scale was applied to a total of 421 adults with ABI who received services in eight Spanish Autonomous Communities (Valencian Region, Andalusia, Navarre, Galicia, Castile-Leon, Madrid, Catalonia, and the Balearic Islands). The inclusion criteria were (a) having suffered an ABI; (b) being 16 years or older; (c) currently attending or previously attended rehabilitation centers or specific centers that offer services and support to this population; and (d) having signed the consent to participate in the study.

According to the sociodemographic characteristics, slightly more than half of the sample were men ($n = 253$; 60%). Their ages ranged from 17 to 91 years ($M = 53.12$; $SD = 14.87$). Half of the sample were married or cohabiting (49.5%), and the most common type of home was the family home (71.4%). According to the clinical data, the date of injury revealed that the mean years since the time of the injury until the present was 8 years ($M = 8.12$, $SD = 7.30$), and the main causes of the ABI were a cerebrovascular accident (56.3%), followed by a traumatic brain injury (21.9%). Other relevant sociodemographic and clinical characteristics are described in Table 1.

The assessment of QoL was performed by the health professionals or relatives who knew the assessed person well. This involved the following inclusion criteria: knowing the person (a) for at least three months; (b) in different contexts; and (c) for prolonged periods of time. The assessment was conducted by 155 informants: 97 of them were professionals (the average number of scales completed by professionals was 6) who worked at 17 centers and organizations (the average number of scales completed by filled by center was 29) located throughout Spain, and 58 were relatives, including partners ($n = 25$), parents ($n = 16$), siblings ($n = 8$), adult sons or daughters ($n = 8$), and friends ($n = 1$). In relation to professionals, most of the sample were women ($n = 77$, 79%), and the most common profession was neuro-psychologist (24.7%). The professionals knew the assessed

Table 1 Sociodemographic and clinical characteristics of the ABI sample ($N = 421$)

	Frequency (%)
Gender	
Male	253 (60%)
Female	168 (40%)
Age (years)	
Mean (SD)	53.12 (14.87)
Range	17–91
Civil status ($n = 420$)	
Married/cohabiting	208 (49.5%)
Single	128 (30.5%)
Separated/divorced	69 (16.4%)
Widow	15 (3.6%)
Educational achievement	
Primary not completed/completed	54 (12.8%)/136 (32.3%)
Secondary not completed/completed	30 (7.1%)/91 (21.6%)
Higher education not completed/completed	11 (2.6%)/99 (23.5%)
Prior/current employment status	
Working	289 (68.6)/12 (2.9%)
Studying	30 (7.1%)/7 (1.7%)
Unemployed	37 (8.8%)/16 (3.8%)
Unable to work	9 (2.1%)/303 (72%)
Retired	54 (12.8%)/79 (18.8%)
Other	2 (0.5%)/2 (1%)
Type of home ($n = 259$)	
Independent flat	35 (13.5%)
Residential center	35 (13.5%)
Sheltered flat	4 (1.5%)
Family home	185 (71.4%)
Type of center	
Day center	116 (27.6%)
Rehabilitation center	227 (53.9%)
Other	22 (5.2%)
Type of support	
Intermittent	66 (15.7%)
Limited	63 (15%)
Extensive	109 (25.9%)
Generalized	183 (43.5%)
Dependency level ($n = 345$)	
Moderate dependency	88 (25.5%)
Severe dependency	129 (37.4%)
Major disability	128 (37.1%)
Time since the injury (years)	
Mean (SD)	8.12 (7.30)
Range	1–57
Location of the injury ($n = 420$)	
Right hemisphere	106 (25.2%)
Left hemisphere	132 (31.4%)
Bilateral	182 (43.3%)

Table 1 (continued)

	Frequency (%)
Etiology of the injury	
Cerebrovascular accident	237 (56.3%)
Traumatic brain injury	92 (21.9%)
Cerebral anoxia	25 (5.9%)
Cerebral tumors	32 (7.6%)
Infection diseases	32 (7.6%)
Other	18 (4.3%)
Length of coma ($n=417$)	
No coma	192 (47.6%)
<1 day	9 (2.2%)
1–3 days	21 (5.0%)
4–28 days	57 (13.7%)
>28 days	44 (10.6%)
No data	94 (22.5%)
Post-traumatic amnesia ($n=418$)	
No amnesia	199 (47.6%)
<1 day	4 (1.0%)
7–9 days	26 (6.2%)
8–30 days	14 (3.3%)
1–3 months	11 (2.6%)
>3 months	31 (7.4%)
No data	133 (31.8%)
Length of rehabilitation Mean (SD) (in months)	
Acute	2.61 (5.58)
Subacute	6.21 (10.03)
Chronic	27.74 (45.20)
Current health conditions	
Physical disability	353 (22.9%)
Sensory disability	212 (13.8%)
Cognitive deficit	367 (23.8%)
Language and communication	201 (13.1%)
Mental health problems/emotional disorder	121 (7.9%)
Behavioral problems	168 (3.2%)
Associated chronic pain	19 (10.9%)
Epilepsy	48 (3.1%)
Others	19 (1.2%)

people for periods between 3 months and 19 years ($M=2.90$, $SD=3.04$; in years), and 81.2% of them had regular contact with the assessed person. In Table 2, the main characteristics of the informants are summarized.

Instrument

The field-test version of the CAVIDACE scale included 120 items, formulated as third-person declarative statements and grouped into the eight core domains (15 items

Table 2 Characteristics of the professionals' sample ($N=97$)

	Frequency (%)
Gender	
Male	20 (21%)
Female	77 (79%)
Type of informant	
Professional	97 (62.6%)
Relatives	58 (37.4%)
Profession	
Neuropsychologist	24 (24.7%)
Occupational therapist	22 (22.7%)
Physiotherapist	11 (11.3%)
Psychologist	9 (9.3%)
Speech therapist	9 (9.3%)
Nursing assistant	7 (7.2%)
Social educator	4 (4.1%)
Nurse	2 (2.1%)
Medical	2 (2.1%)
Social worker	1 (1%)
Pedagogue	1 (1%)
Educational psychologist	1 (1%)
Others	4 (4.1%)
Frequency of contact	
Several times per week	294 (81.2%)
Once a week	38 (10.5%)
Once per 2 weeks	17 (4.7%)
Once a month	13 (3.6%)

per domain) proposed by Schalock and Verdugo. The scale included 12 items that were negatively worded (i.e., EW03, EW04, EW05, EW06, EW08, IR16, PD26, PD27, SD41, SD44, SD45, RI60). The answer format was a four-point scale (*never* = 0, *sometimes* = 1, *often* = 2, and *always* = 3). The scale was completed online or in a hard-copy version, and the administration time was approximately 30 min.

In addition to the 120 specific items for the QoL evaluation, the scale also included the questions about sociodemographic (age, gender, civil status, educational level, employment situation, type of home/center, type of support, and level of dependency) and clinical data (years since the injury, location of the injury, length of coma and post-traumatic amnesia in days, etiology of the lesion, length of rehabilitation, and comorbidity) of the assessed person. It also contained questions concerning the informant and the center or organization in which he/she provided support. An application manual was available for consultation for any aspect. Finally, in the scale, a series of nuances appeared that help to specify and clarify certain items.

Procedure

The recruitment of professionals and participating centers, distributed in different Spanish Autonomous Communities, was conducted by email. The details of the study and the main objectives of the research were specified in the email. Likewise, collaboration was requested for the application of the scales to a large sample of adults with ABI and assistance in recruiting additional ABI professionals through snowball sampling. To attract a large sample of professionals for our study, the request for research collaboration was disseminated through conferences and meetings and posted on the website of the Institute on Community Integration (INICO, University of Salamanca, Spain). All professionals who agreed to participate in the study, either by email or by telephone, reported on the potential number of people with ABI that could be evaluated in their centers.

The second step was to inform each participant about the research project and the procedure in detail and set a deadline. Many professionals preferred to complete the scale in the hard-copy version ($n = 309$), so these were sent by postal mail. For those who preferred to complete the online version of the scale ($n = 180$), a link to access to the online survey was emailed. Regardless of application format (on line or hard copy), all participants received an application manual with specific instructions about the administration of the scale and detailed information about the QoL model on which the instrument is based. Telephone and email contact was constant throughout the process and used when there were doubts and when information needed to be communicated. After the informants returned the completed scales, if there were incomplete data, we re-requested that information by email and telephone.

The research protocol was approved by the Bioethics Committee of the University of Salamanca. Informed consent was obtained by each of the participating centers at the beginning of the study. Personal and clinical data were collected, stored, and protected according to the Organic Law 15/1999 of December 23 for the Protection of Personal Data (LOPD 15/1999), guaranteeing the confidentiality and anonymity of the participants.

Statistical analysis

Psychometric properties of the 120 items were analyzed to select the eight items per domain with the best properties according to five criteria: (a) the mean value of the scores for each of the items and their standard deviation; (b) the number of missing data; (c) the corrected homogeneity indexes (*CHI*); (d) the distribution of the responses; and (e) the content of the items. Negatively worded items were reversed before the analyses.

The reliability of the scale was assessed in terms of internal consistency and inter-rater reliability. One of the most commonly used indicators of internal consistency is Cronbach's alpha [38]. Because this index has been criticized when it is used for ordinal items [39], we also calculated the ordinal alpha from the matrix of polychoric correlations of the items [40]. Inter-rater reliability was tested to compare pairs of ratings made by different independent professionals applying the scale to the same subjects at the same moment and situation [41]. The most common index to assess this property is the Intraclass Correlation coefficient (ICC), which reflects both the degree of correlation and the agreement between measurements.

To provide evidence of the validity of the construct, the internal structure of the scale was analyzed using confirmatory factor analysis (CFA), exploratory structural equation modeling (ESEM; [42]), as well as convergent validity and discriminant validity. Prior to the estimation of the factorial models, several exploratory analyses were carried out in order to obtain a first approximation to the data and detect possible errors and evaluations that could be discarded. According to the results of these preliminary analyses, the data were suitable for the application of factor analysis.

In order to evaluate the fit of the models, we followed the suggestions made by Marsh and Hau [43] and Browne and Cudeck [44] according to which comparative fit index (CFI) and Tucker–Lewis Index (TLI) values above 0.90 and 0.95 and root mean square error of approximation (RMSEA) values below 0.08 and 0.05 indicate acceptable and good levels of fit, respectively. Also, the Bayesian information criterion and Akaike information criterion indexes were taken into consideration (smaller values are preferred).

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS, v.24.0), FACTOR 10.7, and MPlus 7.0.

Results

Item reduction

The analysis of the psychometric properties of the items allowed the selection of those with better functioning within the scale, reducing the initial pool to a more manageable and reliable one. This analysis was based on a series of criteria that were performed by domains.

First, according to the mean and standard deviation criterion, all items with a mean higher than 2.5 were eliminated to decrease the ceiling effect that is often found in the evaluation of QoL. Likewise, items with an excessively low standard deviation were eliminated. This criterion allowed for the elimination of the 16 items with the highest ceiling effect (e.g., i011 “The staff at the centre he/she attends

acknowledge his/her achievements” with $M = 2.6$). The second step was to eliminate those items with a large amount of missing data in the responses, considering them irrelevant or not representative. Only 2 items were eliminated (i.e., i070 “The centre he/she attends supervises the medication he/she takes” and i071 “He/she takes his/her medication as prescribed”) by this criterion because most of them had already been eliminated in the previous step.

The next step was to calculate the *CHI* of the items. This statistical index helps to understand the contribution of each item to the domain to which it belongs. It is calculated by the Pearson product-moment correlation coefficient, using the discrimination index corrected to avoid bias error (i.e., corrected Pearson’s item-total correlation). According to the size of the sample, the minimum value for the selection of the items was set at 0.30 [45]. Fourteen items with scores below 0.30 were eliminated (e.g., i045 “His/her financial resources are insufficient to purchase the support he/she needs”).

We analyzed the distribution of responses to avoid the answers accumulating mainly in one or two response options instead of being distributed in a normal way (i.e., skewness). Fourteen items were eliminated because more than half of the sample was divided between one or two options (e.g., i109 “Other people take his/her things without asking for permission”). Finally, and to avoid compromising content validity, the analysis considered the content of the items to avoid eliminating items especially relevant to this population or items that were duplicated in meaning and content. Ten items were eliminated by this criterion (e.g., i099 “He/she lacks the necessary support to actively take part in his/her community’s life”).

The application of these criteria to the set of 120 initial items allowed us to select the eight items by domain with the best psychometric properties, resulting in a scale composed of 64 items. In Table 3, the process of eliminating

items according to the mentioned criteria, is summarized. In Table 4, the resume of means, standard deviations, corrected item-total correlation and Cronbach’s alpha of items deleted by domains are summarized.

Internal consistency

The Cronbach’s alpha and ordinal alpha values were adequate (Table 5). For the ordinal alpha, coefficients varied between 0.77 (material well-being) and 0.93 (self-determination). Except for emotional well-being, there was a little internal consistency loss for the rest of the domains, with the greatest value lost in physical well-being.

Inter-rater reliability

The analysis of the inter-rater reliability was tested in a sample of 50 adults with ABI. The raters were two independent professionals who applied the CAVIDACE scale to the same subjects in the same period. The ICC value obtained was very high (0.969), with its 95% confidence interval ranging between 0.955 and 0.980. In Table 6, complete information about the results of the ICC calculation is shown.

Confirmatory factor analysis and exploratory structural equation model

Due to the high number of items that constituted each domain ($n = 8$), we used four parcels as indicators or observed variables of each latent variable for the fit analysis of the CAVIDACE scale. Each parcel comprised two items and consisted of the sum of items with asymmetry in opposite directions (positive and negative). In this way, the item with the largest positive asymmetry was assigned to the first parcel along with the item with the largest negative

Table 3 Eliminated items in the final version of the scale

	1st step $M \geq 2.5$	2nd step Missing data	3rd step $CHI < 0.300$	4th step Skewness	5th step Content
EW	i011	–	i006, i007, i008, i009, i010	i012	–
IR	i024, i025	–	–	i017, i018, i021, i023	i030
MW	i031, i032, i036, i037, i044	–	i045	–	i034
PD	–	–	i048, i057, i060	i047, i049, i053, i055	–
PW	i061, i074	i070, i071	i073	i066	i064
SD	i090	–	–	i083, i087, i088	i080, i081, i085
SI	–	–	i095, i100, i101	–	i093, i096, i097, i099
RI	i106, i108, i111, i112, i118	–	i114	i109	–
N items	16	2	14	14	10

EW emotional well-being, IR interpersonal relationships, MW material well-being, PD personal development, PW physical well-being, SD self-determination, SI social inclusion, RI rights

Table 4 Properties of the 64 final items of the CAVIDACE scale by domains

Domain	Item	<i>M</i>	<i>SD</i>	Corrected item-total correlation	Cronbach's alpha if item deleted
EW	1	1.62	0.73	0.52	0.77
	2	1.67	1.00	0.49	0.77
	3	2.20	0.78	0.44	0.78
	4	2.11	0.83	0.51	0.77
	5	2.22	0.71	0.52	0.77
	6	2.25	0.82	0.50	0.77
	7	1.73	0.79	0.49	0.77
	8	1.64	1.12	0.58	0.76
IR	9	1.78	0.88	0.56	0.82
	10	2.06	0.82	0.59	0.82
	11	1.45	0.97	0.33	0.85
	12	1.95	0.83	0.50	0.83
	13	1.41	1.06	0.67	0.80
	14	1.31	1.02	0.73	0.79
	15	1.23	1.00	0.66	0.80
	16	1.89	1.02	0.51	0.82
MW	17	2.25	0.82	0.35	0.77
	18	1.98	0.90	0.38	0.77
	19	2.16	1.00	0.41	0.77
	20	2.47	0.75	0.61	0.73
	21	2.27	0.90	0.52	0.74
	22	2.46	0.72	0.57	0.73
	23	2.46	0.63	0.51	0.75
	24	2.53	0.61	0.56	0.74
PD	25	1.30	0.88	0.66	0.73
	26	1.48	0.92	0.50	0.76
	27	1.59	0.97	0.52	0.76
	28	1.28	0.95	0.49	0.76
	29	1.88	0.81	0.45	0.77
	30	0.98	1.02	0.47	0.77
	31	1.99	0.84	0.34	0.78
	32	1.85	0.89	0.49	0.76
PW	33	2.13	0.81	0.53	0.66
	34	2.34	1.03	0.31	0.71
	35	1.83	0.97	0.45	0.68
	36	2.30	0.77	0.35	0.70
	37	2.14	0.90	0.50	0.67
	38	2.35	0.82	0.43	0.68
	39	2.54	0.71	0.39	0.69
	40	2.10	0.78	0.32	0.70
SD	41	1.75	1.00	0.75	0.89
	42	1.95	1.02	0.60	0.91
	43	1.65	1.04	0.77	0.89
	44	1.99	1.10	0.71	0.90
	45	1.80	1.08	0.82	0.89
	46	2.04	1.00	0.74	0.89
	47	1.29	1.07	0.79	0.89
	48	2.04	0.98	0.46	0.92

Table 4 (continued)

Domain	Item	<i>M</i>	<i>SD</i>	Corrected item-total correlation	Cronbach's alpha if item deleted
SI	49	1.35	1.05	0.59	0.87
	50	1.68	0.96	0.63	0.86
	51	1.76	0.95	0.70	0.85
	52	1.60	0.95	0.50	0.87
	53	1.41	0.91	0.62	0.86
	54	1.41	0.89	0.74	0.85
	55	1.32	0.90	0.73	0.85
	56	1.89	0.97	0.58	0.86
RI	57	2.53	0.70	0.42	0.68
	58	2.28	0.78	0.34	0.70
	59	1.82	1.09	0.31	0.72
	60	2.43	0.79	0.38	0.69
	61	2.07	0.97	0.50	0.66
	62	2.47	0.76	0.48	0.67
	63	2.76	0.50	0.35	0.70
	64	2.59	0.63	0.56	0.66

EW emotional well-being, *IR* interpersonal relationships, *MW* material well-being, *PD* personal development, *PW* physical well-being, *SD* self-determination, *SI* social inclusion, *RI* rights

asymmetry, and the items with the next largest asymmetry were assigned to the second parcel (Table 7).

Next, the fit of four CFA models was compared. These models were specified based on those proposed in Gómez et al. [19]: (a) QoL as a unidimensional construct (M1); (b) QoL as eight first-order correlated factors (M2) [15]; and (c) QoL as eight first-order factors and a general second-order factor of QoL (M3) [46]. Finally, a bifactor model (M4) [47] representing an alternative specification of M3 was estimated. The models were estimated using robust maximum likelihood (MLR) implemented in Mplus 7.0. In the estimation of the models, non-independence between the observations made by the same evaluators was considered (i.e., type = COMPLEX within MPlus). The results are displayed in Table 8.

The unidimensional model obtained an unacceptable fit to the data (RMSEA = 0.122, CFI = 0.567, SRMR = .108). Compared to the others, the eight correlated first-order factors showed a better fit in general terms than the hierarchical model (Δ RMSEA = -0.009, Δ CFI = 0.046) and was more plausible according to absolute fit indexes such as *AIC* (Δ AIC = -283), *ABIC* (Δ ABIC = -245), and *BIC* (Δ BIC = -202). The bifactor model was unable to reach convergence. Considering all fit indices, the eight first-order correlated factor model was the best model. However, the *CFI* of the eight-domain model was below the desirable cut-off point. We investigate local misfit sources by inspecting the modification indexes (MI) and their standardized expected parameter changes (SEPC). 47 IM met the criteria

Table 5 Comparison of Cronbach's alphas for the field-test version and the final version of the scale

	EW	IR	MW	PD	PW	SD	SI	RI
Cronbach's alpha								
Field-test version	0.74	0.87	0.79	0.82	0.75	0.93	0.87	0.74
Final version	0.80	0.84	0.77	0.79	0.71	0.91	0.87	0.71
Difference	+0.06	-0.03	-0.02	-0.03	-0.04	-0.02	0	-0.03
Ordinal alpha								
Field-test version	0.80	0.90	0.78	0.86	0.86	0.94	0.91	0.84
Final version	0.84	0.88	0.77	0.83	0.81	0.93	0.90	0.82
Difference	+0.04	-0.02	-0.01	-0.03	-0.05	-0.01	-0.01	-0.02

EW emotional well-being, IR interpersonal relationships, MW material well-being, PD personal development, PW physical well-being, SD self-determination, SI social inclusion, RI rights

Table 6 Results of ICC calculation, single-rating, absolute-agreement, and 2-way random-effects model

	Intraclass correlation	95% Confidence interval		F-test with true value 0			
		Lower bound	Upper bound	Value	df1	df2	Sig
Single measures	0.969	0.955	0.980	45.850	49	6223	0.000

Table 7 Composition of parcels

	Parcel 1	Parcel 2	Parcel 3	Parcel 4
Emotional well-being	i01 (0.35)	i07 (0.08)	i02 (-0.15)	i08 (-0.24)
	i06 (-0.85)	i04 (-0.73)	i03 (-0.67)	i05 (-0.66)
Interpersonal relationships	i15 (0.40)	i14 (0.27)	i13 (0.21)	i11 (0.04)
	i16 (-0.53)	i10 (-0.33)	i09 (-0.18)	i12 (-0.08)
Material well-being	i18 (-0.51)	i23 (-0.80)	i19 (-0.84)	i17 (-0.91)
	i20 (-1.36)	i22 (-1.29)	i21 (-1.1)	i24 (-0.94)
Personal development	i30 (0.72)	i25 (0.17)	i28 (0.14)	i32 (-0.13)
	i31 (-0.37)	i27 (-0.26)	i29 (-0.21)	i26 (-0.17)
Physical well-being	i40 (-0.38)	i35 (-0.41)	i33 (-0.65)	i37 (-0.78)
	i39 (-1.50)	i34 (-1.38)	i38 (-1.16)	i36 (-0.86)
Self-determination	i47 (0.25)	i43 (-0.18)	i41 (-0.34)	i45 (-0.40)
	i44 (-0.65)	i46 (-0.64)	i48 (-0.57)	i42 (-0.56)
Social inclusion	i55 (0.34)	i53 (0.25)	i49 (0.24)	i54 (0.21)
	i56 (-0.38)	i51 (-0.17)	i52 (-0.13)	i50 (-0.09)
Rights	i59 (-0.42)	i61 (-0.61)	i58 (-0.75)	i64 (-1.35)
	i63 (-2.25)	i57 (-1.46)	i60 (-1.45)	i62 (-1.36)

Asymmetry values are between parentheses

Table 8 Standardized factorial loadings for the eight-domain confirmatory model

Model	FP	χ^2	RMSEA (CI)	CFI	TLI	SRMR	AIC	BIC	ABIC
M1 (one-dimensional)	96	3358.2	0.122 (0.118–0.126)	0.567	0.537	0.108	43,947	44,335	44,031
M2 (eight correlated factors)	124	1203	0.065 (0.060–0.068)	0.890	0.869	0.071	41,594	42,095	41,702
M3 (second-order factor)	104	1495.8	0.074 (0.069–0.078)	0.844	0.831	0.094	41,877	42,297	41,947
M4 (bifactor)	nc								
M5 (ESEM eight correlated factors)	292	455.5	0.041 (0.034–0.047)	0.972	0.948	0.019	41,054	42,238	41,308

FP free parameters from the base-line model, χ^2 chi-square, RMSEA root mean square error of approximation, CFI comparative fit index, TLI Tucker–Lewis index, SRMS Standardized root mean square residual, AIC akaike information criterion, BIC Bayesian information criterion, ABIC sample size-adjusted BIC, nc no convergence, ESEM exploratory structural equation model

of relevance ($IM > 10$ and $SEPC > 0.20$), according to the recommendations of Saris et al. [48], and most of them referred to cross-loadings set at zero in the confirmatory model. Given that the assumption of the independent cluster model of confirmatory factor analysis that the observable variables are pure indicators of their factor may be in practice in excess restrictive [49], we estimate an ESEM model with eight correlated factors and target rotation (Fig. 1). The fit of the model was substantially better than that of its confirmatory counterpart ($RMSEA = 0.041$; $CFI = 0.972$; $TLI = 0.948$), suggesting that setting all factor loads to zero in the confirmatory model led to an accumulation of small errors of specification with high impact on model fit. The

only exception was the BIC, which in ESEM was higher than in the CFA model, possibly due to the high sensitivity of the BIC to model parsimony (number of estimated parameters). Table 9 shows the factor loads of the ESEM model. The model was able to recover quite clearly the theoretical structure of the construct, since the target loads were significant ($p < 0.05$) and, except two cases, greater than 0.30 (with mean 0.62), and the few significant cross-loadings acquired insignificant or low values (mean 0.14). To assess the convergent validity of ESEM factors, we estimate the explained common variance (ECV) by the target parcels in each theoretical factor. The ECV values (Table 9) were between 0.74 and 0.95 ($M = 0.87$), suggesting that in all cases the primary parcels explained a common amount of variance substantially greater than that captured by the parcels not related to the factor. Thus, for example, in the self-determination factor, the parcels theoretically associated to it explained 91% of their common variance, while cross-loadings accounted for 9%.

Standardized factorial loadings, model-based reliability (McDonald's omega), and an estimation of convergent validity for the factors using the average variance extracted (AVE) are shown in Table 10. The factorial loadings ranged from 0.46 to 0.90. Omega indices were between 0.77 (MW and PW) and 0.91 (SD). AVE values were close to or greater than 0.50 [50], suggesting good convergent validity of the factors.

Finally, the correlations between the factors (Table 11) showed a range between 0.31 (PW-SI) and 0.86 (PD-SD). Discriminant validity was checked by comparing the highest correlation with the square of the AVE value in each factor (see diagonal of Table 11). For a factor to be considered to have adequate discriminant validity, the square of the AVE value must be greater than the highest observed correlation in that factor [50], a condition that was met in most cases.

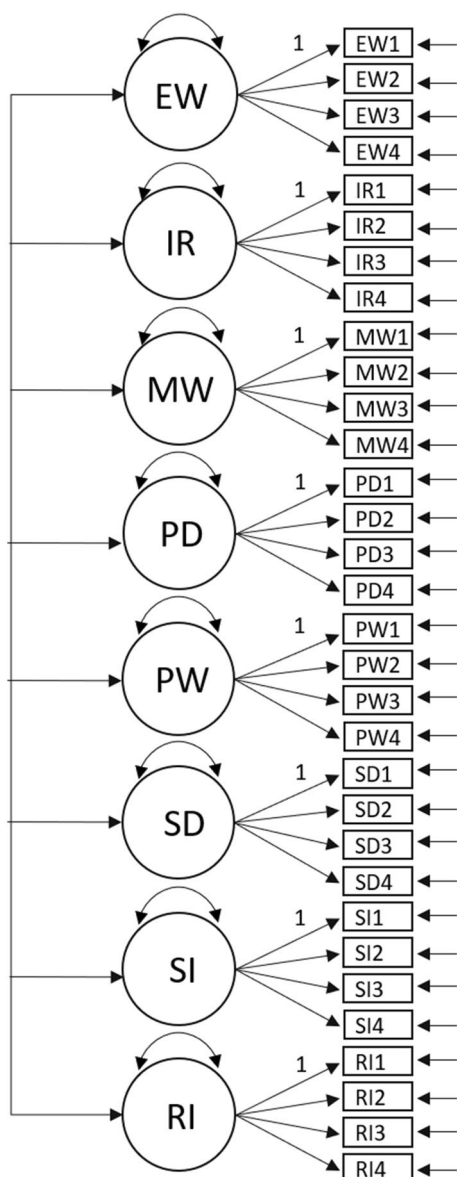


Fig. 1 Conceptual representation of eight first-order correlated factors ESEM model

Discussion

The main objective of this paper was to describe the validation process of the CAVIDACE scale, a QoL measurement instrument to be used with ABI population to improve personal outcomes and guide support and interventions. The results suggest that the CAVIDACE scale has good psychometric properties in our sample with adequate evidence of validity and reliability.

The internal consistency was good to excellent for all subscales, and the values obtained with the field-test version of the scale (120 items) were very similar to those obtained in the final version (64 items). In this way, reliability did not decrease significantly with reduction of the number of items, obtaining a user-friendly scale in terms of time without scarifying internal consistency. According to the inter-rater

Table 9 Factor loads of the ESEM model

Parcel/factor	EW	IR	MW	PD	PW	SD	SI	RI	ECV (par)	ECV (cr)
P1	0.58	0.16	0.00	0.13	0.05	-0.07	0.02	0.07	0.88	0.12
P2	0.48	0.02	0.02	0.16	0.19	0.08	0.13	-0.12		
P3	0.63	-0.06	0.07	0.10	-0.02	0.14	0.10	0.01		
P4	0.85	0.04	-0.10	-0.10	-0.05	0.03	-0.02	0.02		
P5	0.04	0.76	-0.04	0.05	-0.05	0.03	0.05	0.01	0.95	0.05
P6	-0.07	0.91	-0.04	0.01	0.05	0.00	0.06	-0.02		
P7	0.07	0.81	-0.01	-0.03	0.02	-0.04	0.01	0.03		
P8	0.12	0.36	0.23	-0.01	0.02	0.02	0.04	0.07		
P9	0.06	-0.07	0.80	-0.03	-0.03	0.05	0.04	0.07	0.80	0.20
P10	0.01	0.11	0.58	-0.06	0.17	-0.10	0.02	0.06		
P11	-0.16	0.05	0.48	0.08	0.04	0.29	0.24	-0.16		
P12	-0.01	0.02	0.49	0.11	0.10	-0.20	0.01	0.10		
P13	-0.11	-0.02	-0.12	0.51	0.08	0.07	0.22	0.18	0.74	0.26
P14	0.17	0.16	0.10	0.44	-0.12	0.28	-0.15	-0.02		
P15	-0.02	0.11	0.23	0.39	-0.07	0.14	-0.02	0.04		
P16	0.19	-0.03	-0.04	0.81	0.11	-0.07	0.04	-0.07		
P17	0.13	-0.01	0.09	-0.13	0.67	0.12	0.04	0.06	0.87	0.13
P18	-0.03	0.00	0.17	0.04	0.25	-0.16	-0.03	0.15		
P19	-0.02	0.05	0.15	0.11	0.43	-0.18	-0.07	0.12		
P20	-0.02	0.02	-0.07	0.04	0.97	0.08	-0.02	-0.07		
P21	0.07	0.02	-0.01	0.15	-0.02	0.68	0.09	0.05	0.91	0.09
P22	0.06	0.04	0.04	0.05	0.07	0.76	-0.01	0.08		
P23	0.00	0.04	0.10	0.20	-0.03	0.51	0.03	0.20		
P24	0.14	0.05	-0.01	0.05	0.01	0.74	0.06	0.01		
P25	0.10	0.00	0.07	0.17	-0.07	-0.11	0.73	0.08	0.95	0.05
P26	0.00	0.03	0.04	-0.02	-0.01	0.06	0.81	0.00		
P27	0.02	0.01	0.09	-0.03	0.06	0.08	0.63	0.01		
P28	0.04	0.17	0.01	-0.07	0.01	-0.02	0.78	-0.01		
P29	-0.10	0.09	0.05	0.25	0.04	0.28	-0.01	0.17	0.85	0.15
P30	-0.02	-0.03	-0.04	0.02	-0.01	0.10	0.15	0.76		
P31	0.08	-0.02	0.15	0.01	0.06	0.05	-0.07	0.48		
P32	0.00	0.10	-0.02	-0.06	0.06	0.01	-0.04	0.76		

ECV (par) Explained common variance captured by the targeted loadings, *ECV (cr)* explained common variance captured by non-targeted loadings (cross-loadings), *EW* emotional well-being, *IR* interpersonal relationships, *MW* material well-being, *PD* personal development, *PW* physical well-being, *SD* self-determination, *SI* social inclusion, *RI* rights

Italics: statistically significant loads ($p < 0.05$), bold italics: targeted loadings

Table 10 Standardized factorial loadings for the eight-domain confirmatory model

	EW	IR	MW	PD	PW	SD	SI	RI
Parcel 1	0.737	0.815	0.763	0.601	0.778	0.881	0.821	0.471
Parcel 2	0.753	0.897	0.732	0.770	0.455	0.848	0.851	0.767
Parcel 3	0.767	0.838	0.583	0.646	0.616	0.783	0.712	0.596
Parcel 4	0.677	0.570	0.629	0.788	0.837	0.879	0.859	0.729
AVE	0.54	0.62	0.46	0.50	0.47	0.72	0.66	0.42
Omega	0.82	0.87	0.77	0.80	0.77	0.91	0.89	0.74

AVE average variance extracted, *EW* emotional well-being, *IR* interpersonal relationships, *MW* material well-being, *PD* personal development, *PW* physical well-being, *SD* self-determination, *SI* social inclusion, *RI* rights

Table 11 Correlations between the eight domains

	EW	IR	MW	PD	PW	SD	SI	RI
EW	0.73							
IR	0.66 (0.04)	0.79						
MW	0.34 (0.05)	0.44 (0.04)	0.68					
PD	0.75 (0.03)	0.55 (0.04)	0.48 (0.06)	0.71				
PW	0.41 (0.05)	0.42 (0.05)	0.62 (0.04)	0.35 (0.05)	0.69			
SD	0.63 (0.03)	0.49 (0.04)	0.38 (0.06)	0.86 (0.02)	0.19 (0.05)	0.85		
SI	0.50 (0.05)	0.69 (0.03)	0.53 (0.05)	0.58 (0.04)	0.31 (0.05)	0.56 (0.04)	0.81	
RI	0.33 (0.05)	0.46 (0.04)	0.66 (0.04)	0.51 (0.05)	0.45 (0.05)	0.48 (0.05)	0.42 (0.04)	0.65

Square root of the AVE is on the diagonal (in bold), and the inter-factor correlations are out of the diagonal
EW emotional well-being, *IR* interpersonal relationships, *MW* material well-being, *PD* personal development, *PW* physical well-being, *SD* self-determination, *SI* social inclusion, *RI* rights

reliability analyses, we can conclude that the observers were consistent in their responses, probably because they faithfully followed the administration instructions provided in the manual and because they were all familiar with the QoL model in use.

The results supported the internal structure of the scale based on the theoretical and assessment framework in which QoL is composed of eight intercorrelated first-order domains. This first-order multidimensional model showed better fit than the one-dimensional model and second-order models of QoL. In this way, the results of our study are aligned with all those [19, 30, 51, 52] contradicting the recently proposed solutions of the eight domains organized in three second-order factors [46]. In this sense, this research provides more lines of evidence about the better fit of the most parsimonious multidimensional solution in comparison to the hierarchical ones.

However, the final model showed a sub-optimal CFI (0.89) according to the most widely used cut-off (0.95) [53]. One possible reason for this result is the complexity of the model itself combined with the overly restrictive assumptions of the independent-clusters model of CFA (e.g., that all the cross-loadings are exactly zero) [49]. In such a model, the accumulation of multiple but small and non-substantive errors of specification can lead to a substantial decrease in fit [54]. Taking this into account, we explore the hypothesis by estimating less restrictive factorial model (i.e., exploratory structural equation modeling) [42], whose fit of the model was substantially better. In addition, it is necessary to consider that, paradoxically, sometimes CFI and RMSEA tend to penalize models with better measurement quality (i.e., with higher factor loadings) [55] and that the cut-off values traditionally used to judge fit are largely arbitrary [56].

With respect to convergent and discriminant validity, the self-determination domain stood out [51], while rights [51, 52] and material well-being were the least discriminant. The results obtained for these domains were also found in previous studies with other QoL instruments for other populations

with disabilities [51, 52] and might be explained by the fact that most of social services have been traditionally aimed at satisfying basic needs and therefore material well-being contents that are being assessed might be achieved for most of the participants. In relation to the low discrimination of rights, explanations are harder to be provided. Perhaps, items are formulated in a too generic way and they should be more specific to really discriminate between participants. Moreover, this domain might be influenced by respondents' bias such as desirability and might be much more discriminant if it were answered by people with ABI. Discriminant lines of evidence, together with the worst fit of the second-order model, suggest that the domains of QoL are empirically separable [52]. Furthermore, these results support the conclusion that the items that make up the scale constitute an appropriate operationalization of the QoL construct for adults with ABI who are attending social services in our country. Thus, it seems to be an appropriate and helpful tool for guiding evidence-based practices whose main utility is to provide the best available evidence to make clinical and organizational decisions [57].

Some limitations of the study should be emphasized. First, the recruitment process of the participants was based on convenience and snowball sampling. These procedures allow us to obtain an appropriate group of a global network of ABI professionals and are effective for recruiting a representative sample of the ABI population, which was especially relevant for our study. Nevertheless, the non-probabilistic nature of the sample suggests caution in generalizing the results to the population. Second, this evaluation is a report from a third person (professionals/relatives) when the subjective perspective is crucial in the assessment of QoL. In this regard, we are already working on a parallel version of the CAVIDACE scale to be completed by people with ABI. Third, in this study, we focused on providing reliability and validity evidence based on the internal structure of the scale. However, it would be desirable to complement them with evidence

from other alternative analytic approaches such as Item Response Theory. Four, we consider one of the greatest limitations of this study is not having carried out a study to provide concurrent validity evidence through the application of the CAVIDACE together with an existing health-related-QoL instrument. Future studies will be aimed at providing evidence of concurrent validity and sensibility of the instrument to detect changes in QoL outcomes due to interventions and individualized supports. Finally, we did not check the possible effect that administration format (hard copy vs. online) or the type of respondents (professionals vs. relatives) may have on the scores. These aspects will be also goals of future studies.

The scale validation adheres to the majority of methodological standards proposed in the COSMIN checklist [58], covering the following aspects: (a) internal consistency and inter-rater reliability, presented in this paper; (b) content validity through a Delphi study [27]; and (c) construct validity, based on a CFA. Criterion validity and responsiveness were not assessed in this study despite being one COSMIN's standard. This will be pursued in a future line of research.

In conclusion, the results of this study provide support for the good psychometric properties of the CAVIDACE scale, which can be a useful measure of QoL outcomes in the clinical and research contexts and, therefore, in the personal sphere. With regard to the clinical context, the use of an evaluation scale based on a global and systemic approach that considers the main needs of the person will help professionals plan and guide the provision of services and individualized rehabilitation in a more appropriate manner. In terms of the research context, the results obtained from the application can be considered key and comparable information that will greatly help improve the understanding of the condition. Finally, considering people with ABI and their relatives as the central axis of the activities will contribute to focusing rehabilitation and support to meet the desires of people with ABI, potentially leading to improvement in the QoL. Future research can validate and adapt the CAVIDACE scale to different languages and contexts.

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Compliance with ethical standards

Conflict of interest There are no any financial or any other type of conflicts of interest for the authors of this manuscript.

Ethical approval Ethics procedures have been followed, and the standards governing research involving human participants in force in Spain have been met.

Informed consent Informed consent was obtained from all individual participants included in the study.

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