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Adaptation into spanish of the Clinically Useful Depression Outcome Scale (CUDOS) for assessing major depressive disorder from the patient's perspective

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Objective: To adapt the CUDOS scale (Clinically Useful Depression Outcome Scale) into Spanish and to test its psychometrical properties in a sample of patients with major depressive disorder (MDD).

Methods: A two-step cross-sectional, multicenter validation study was conducted (linguistic adaptation into Spanish and psychometric validation). The study evaluated patients attended in Primary Care with a MDD diagnosis within the last 3 months (DSM-IV TR criteria). The following scales were administered: CUDOS, PRIME-MD (Primary Care Evaluation of Mental Disorders), HAMD-17 (Hamilton Depression Rating Scale), SOFAS (Social and Occupational Functioning Assessment Scale), SF-36 (Physical –PCS- and Mental –MCS- Component Summaries), and the CGI-S & PGI-S (Clinical Global Impression for Severity of Illness scales for clinicians and patients, respectively). Feasibility, reliability, and validity of the Spanish version were assessed.

Results: In the validation study, 305 MDD patients (69.5% female) with a mean age (standard deviation-SD-) of 51.75(15.53) were included. Mean completion time was 4.47(2.4) minutes. Floor or ceiling effects were found in less than 1% of the case scores. Internal consistency was adequate (Cronbach´s α= 0.88). Pearson correlation coefficients with CUDOS were: -0.42 (SOFAS), 0.45 (HAMD-17), -0.22 (PCS), -0.65 (MCS); all p<0.001. The CUDOS properly discriminated among clinical severity levels (p<0.03).

Conclusions: The adapted Spanish version of the CUDOS shows adequate psychometric properties as an evaluation instrument of major depression from the patient's perspective.

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Key words: Major depressive disorder, Psychometric validation, Primary care, CUDOS

Actas Esp Psiquiatr 2013;41(5):287-300

Adaptación al castellano de la escala Clinically Useful Depression Outcome Scale (CUDOS) para la evaluación de la depresión mayor desde la perspectiva del paciente

Objetivo: Adaptar al castellano la escala CUDOS (*Clinically Useful Depression Outcome Scale*) y analizar sus propiedades psicométricas en pacientes con trastorno depresivo mayor (TDM).

Método: Se realizó un estudio multicéntrico transversal de dos etapas (adaptación cultural y validación psicométrica) en el que se evaluaron pacientes en Atención Primaria con TDM diagnosticado (criterios DSM-IV TR) en los últimos 3 meses. Junto a la escala CUDOS, se aplicaron los instrumentos: PRIME-MD (*Primary Care Evaluation of Mental Disorders*), HAMD-17 (*Hamilton Depression Rating Scale*), SOFAS (*Social and Occupational Functioning Assessment Scale*), SF-36 (Componentes Físico–PCS- y Mental–MCS-) y escalas CGI-SI y PGI-SI (Escala de Impresión Clínica Global de Gravedad según clínico o paciente, respectivamente). Se analizó la factibilidad, fiabilidad y validez de la versión adaptada.

Resultados: En la fase de validación, se incluyeron 305 pacientes (69,5% mujeres) con edad media (desviación típica) de 51,75(15,53) años. El tiempo medio de cumplimentación fue de 4,47(±2,4) minutos. Los efectos techo/suelo se encontraron en menos del 1% de los casos. La consistencia interna de la escala CUDOS fue adecuada (α de Cronbach=0,88). Los coeficientes de correlación de Pearson de CUDOS con otras escalas fueron: 0,42 (SOFAS); 0,45 (HAMD-17); -0,22 (PCS); -0,65 (MCS); p<0,001. La escala CUDOS discriminó adecuadamente entre los diferentes niveles clínicos de gravedad (p<0,03).

Conclusiones: La versión adaptada de la escala CUDOS muestra propiedades psicométricas adecuadas como instrumento de evaluación de la depresión mayor desde la perspectiva del paciente.

Palabras clave: Trastorno depresivo mayor, Propiedades psicométricas, Atención primaria, CUDOS

INTRODUCTION

Major depressive disorder (MDD) is the most frequent mental disorder in Spain, with an estimated prevalence in the adult population of 3.9% yearly and 10.6% over the life time.[1,2] Although these data are subject to some variability according to the methodology used and the population or care setting of reference, their relevance from the epidemiological point of view is clear.[3-5] The personal suffering, morbidity and probability of recurrence and the impact on the family and socio-laboral life and associated risk of suicide of MDD patients are known.[6-11] All these factors contribute to the elevated socio-health care and economic burden of the disorder in our country.[12-14]

The efforts of clinical research in major depression are focused on establishing an adequate diagnosis and treatment in order to maximize the effectiveness of the therapeutic interventions. In this way, the possibilities of achieving complete remission of the symptoms, which has been associated with a better prognosis in terms of relapses and morbidity-mortality would be reinforced.[10,13,15,16] In accordance with these purposes, recent health strategies and therapeutic guidelines have recommended a first approach to the disorder from the Primary Care (PC) setting.[13,15] However, it is precisely within this context where the greatest problems are found.[17,18] For example, it has been shown that only 34% of the patients are finally treated with antidepressants in this setting.[19] This gives even more interest to being able to identify those individuals with MDD symptoms early and to begin an adequate therapeutic approach.[20,21]

Regulatory agencies are currently interested in the measurements of the results perceived by the patient in order to make a comparative evaluation of the benefits of the drugs.[15,22] The subjective elements are as important or more for the patient than the biological ones, thus, a rigorous evaluation of them is necessary.[23] Reliable and simple self-applicable instruments are fundamental for the structured and systematic collection of this information and also make it possible to convert the patient into a participant in the therapeutic process, improving the efficiency of the medical consultation. [23-25] For this reason, the CUDOS scale (*Clinically Useful Depression Outcome Scale*) was designed in the USA, [26-28] within the MIDAS project (Rhode Island Methods to Improve Diagnostic Assessment and Service) with the aim to develop useful instruments for the clinical practice. This is a brief instrument made up of 18 5-point Likert type questions that can be rapidly answered.[29] It is easy to correct and the total score is calculated by ading up the scores of the first 16 items (range from 0 - minimum of depressive symptoms - to 64 - maximum symptomatic intensity). Regarding its content validity, it includes the entire spectrum of MDD symptoms, defined by the DSM-IV classification and also collects information on functional aspects and quality of life (items 17-18). Regarding its psychometric properties, it has become evident that it has adequate convergent reliability and validity. Furthermore, it discriminates between clinical levels of severity of depression, being sensitive to the changes in the condition of the patient.[26,28]

In order to provide evidence that allows the health care professionals of our country to evaluate the use of this scale in the clinical practice, the current work presents the cultural adaptation of this instrument and the initial analysis of its reliability and validity for clinical evaluation of MDD in the PC consultation.

METHODOLOGY

A multicenter, observational cross-sectional study implemented under the usual clinical practice conditions in 44 PC centers of different regional communities in our country was conducted. The study protocol was approved by the Ethics Committee of the Ministry of Health of the Galicia Government.

Sample

Each investigator included the first patients consecutively according to arrival to the medical consultation who fulfilled the selection criteria and gave their informed consent. A total of 338 adult patients who had been diagnosed of MDD (DSM-IV TR criteria)[30] during the last three months were interviewed. The patients must have had symptoms of MDD or MDD in partial remission in accordance with the PRIME-MD scale[31,32] and sufficient cognitive capacities to answer the study questions. Those patients who were not capable of filling out the scales due to underlying medical disease and those who had participated in a clinical trial in the previous six months were excluded.

After the analysis of the selection criteria, 33 cases had to be excluded either because they had not been diagnosed of MDD during the last three months (N=14) or because the diagnosis did not adapt to the DSM-IV TR criteria (N=19). Thus, the final valid sample for this study was made up of 305 patients.

The study was conducted in two stages in accordance with the already commented purposes of the project:

Stage I. Linguistic adaptation to our country of the original version in English

The work done in this phase is summarized in figure 1. Linguistic adaptation was performed following the recommendations of the specialized scientific societies.[33] There was a multidisciplinary coordinator team made up by experts in the diagnosis and treatment of these patients and by experts in the development of instruments for the evaluation of outcomes and health.

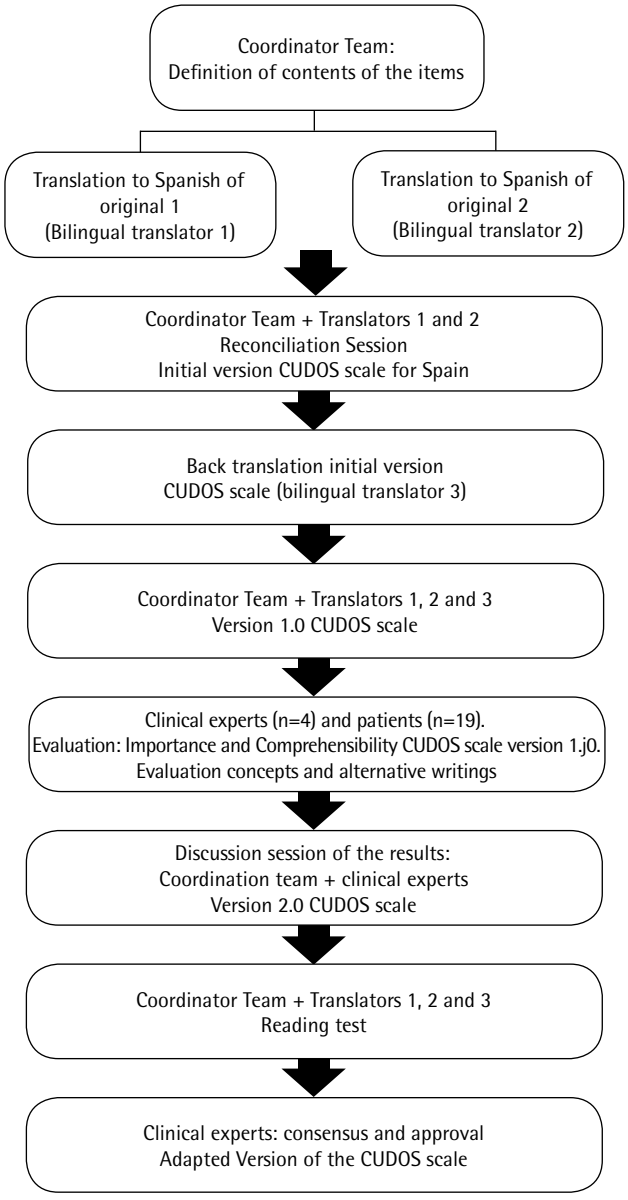


Figure 1 | *Linguistic adaptation of the CUDOS Scale*

Using a conceptual harmonization of the questions on the scale, the version was presented to a panel of physicians (n= 4) and to patients diagnosed of MDD in accordance with the DSM-IV-TR criteria (n=19). Both groups scored the importance and comprehensibility of each item on two scales with the following range: 0 -minimum importance/ null compensability - to 4 -maximum importance/optimal comprehensibility. They were also offered the opportunity to suggest alternative forms of writing to approach each aspect collected. After analyzing this information (figure 2), a final version that was reviewed by the translators and approved by all of the participating clinicians was agreed on. In this way, the adaptation to Spanish of the scale was completed (Annex).

Stage II. Analysis of the psychometric properties of the adapted version

In this second stage, the investigators gathered socio-demographic and clinical information from each participant and confirmed the diagnostic adequacy of MDD in accordance with the DSM-IV-TR criteria. During the visit contemplated in the protocol, they also applied the following measurements:

a. Mood state module of the instrument Primary Care Evaluation of Mental Disorders (PRIME-MD).[31,32] The mood state module applied was made up of 17 dichotomic questions that made it possible to distinguish between the presence of a MDD, a state of partial remission or recurrence, dysthymia, minor depression, bipolar affective disorder or a depression of drug etiopathogeny or due to physical disorder.

b. Hamilton Depression Rating Scale, 17-item version (HAMD-17).[34,35] This scale makes it possible to evaluate the severity of the symptoms and the changes of the patient over time. The total score has a range going from 0 to 52 points (the higher, the score the higher the severity). The following cutoffs were recommended: not depressed: 0-7; Mild/minor depression: 8-13; Moderate depression: 14-18; Severe depression: 19-22; Very severe depression: $\geq$ 23.[35,36]

c. Clinical Global Impression -for Severity (CGI-S).[37] It evaluates the severity of the clinical picture of the patient using an 8-level Likert scale (from 0-data evaluation up to 7-extremely ill).

d. Social and Occupational Functioning Assessment Scale (SOFAS).[38] This scale evaluates social and occupational functioning of the patient without taking the present symptoms into account. The scores range from 1 point (subject with no or extremely limited social performance) to 100 (the best social functioning. A score superior to or equal to 80 was recently established as a valid cutoff to define normalized social functioning.[10]

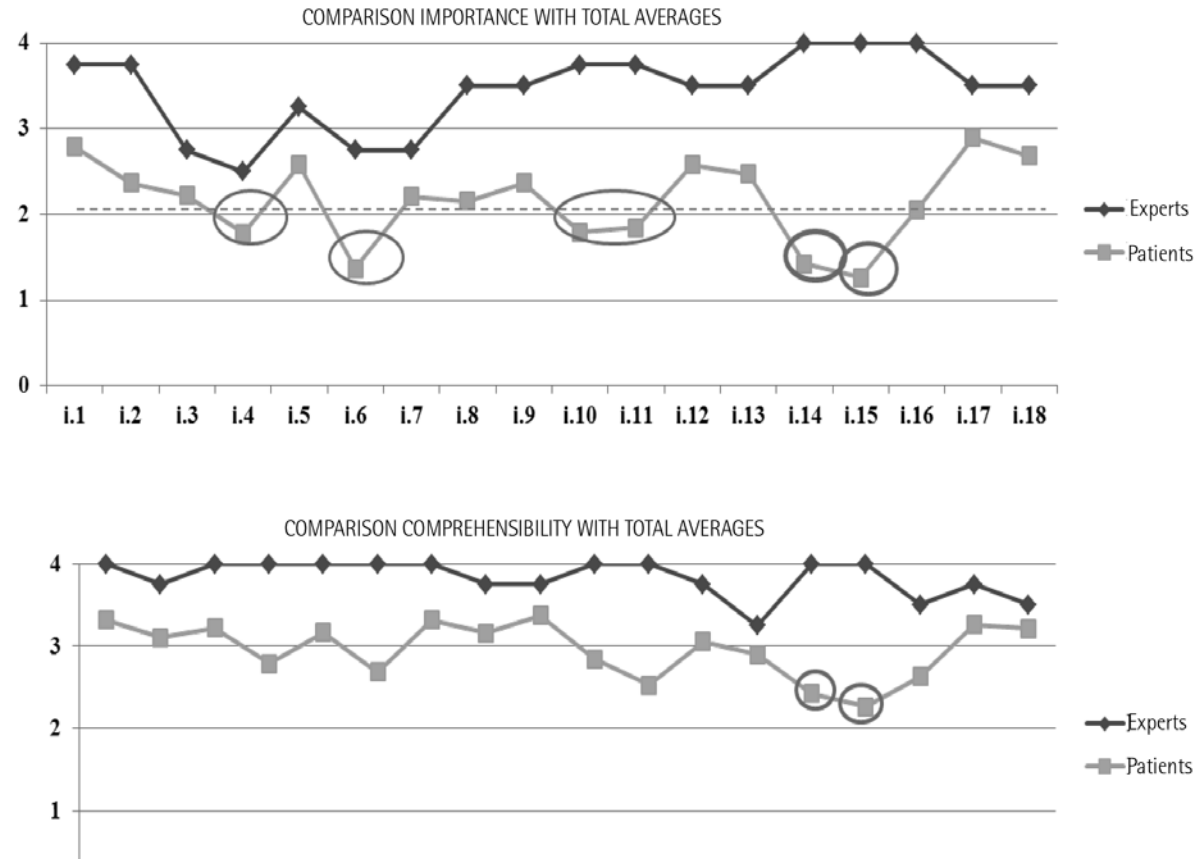


Figure 2 | *Importance and understandability of the CUDOS scale according to clinical experts (n=4) and patients (n=19)*

On their part, the patients reported the presence of personal situations standing out in the scientific literature as possible risk factors (family backgrounds, severe problems of close persons - economic or work problems and cohabitation).[39,40] They also filled the following:

Measurements filled out by the patients

a. SF-36 Questionnaire.[41,42] A generic instrument on health-related quality of life (HRQL) validated in our country and widely used in the general population and different groups of patients. It is made up of 36 questions whose scores are grouped into two summary components, physical (PCS) and mental (MCS) with standardized scores for the general Spanish population and normalized to a distribution 50±10.
b. Patient Global Impression Severity Scale (PGI-SI):[37] Likert type scale in which the patient evaluates his/her global state with scores ranging from 0 (not evaluated) and 7 points (extremely ill).
c. Version of the scale CUDOS adapted to Spanish (Annex):[26-28] The total score is the sum of the answers to the 16 questions. The theoretical range of the scores goes from 0 to 64 points. Higher scores are indicative of greater of greater severity of the depressive picture. In accordance with the authors of the original version, the global scores can be classified into 5 levels of severity: without depression (0-10 points), minimum(11-20), mild (21-30), moderate (31-45), severe (≥46).

Sample size

The number of cases needed to evaluate was estimated according to the percentage of patients who responded to the treatment or were in partial remission after it (approximately 33%,), according to the original work.[27] Based on this information, at least 176 patients were considered for inclusion in order to perform the analysis of the differences of means between independent groups with

Table 1 Description of the sample (n= 305)

		n	%
Gender	Woman	212	69.5
Academic training	No studies	46	15.1
	Secondary school	46	15.1
	School graduate studies	101	33.1
	Upper vocational /university training	59	19.3
	Secondary education	53	17.4
Cohabitation	Alone	37	12.1
	Accompanied in family	267	87.5
	In institution	1	0.3
Previous depressive episodes, (yes)		126	41.3
Family background of depression, (yes)		116	38.0
Severe problems of close persons, (yes)		93	30.5
Financial or work problems, (yes)		119	39.0
Problems of cohabitation or family, (yes)		90	29.5
Medications - stress or anxiety, (yes)		201	65.9
Antidepressant treatment, (yes)		267	87.5
Result PRIME-MD classification	MDD	258	84.6
	MDD in partial remission	47	15.4

a statistical power of 80%, for an effect size of 0.4 and a confidence level (1-α) of 95%. In addition, it was assumed that a percentage of patients (33%) for whom the required minimum time to evaluate the treatment response (6 to 12 weeks) will not be reached, would participate in the study. Thus, and foreseeing a common percentage of invalid cases for this type of study (10%), a minimum number of 290 patients was considered to be necessary.

Statistical analysis

In the first place, the clinical and socio-demographic characteristics of the whole sample included in the second stage were described using statistics of central tendency and dispersion in the quantitative variable and frequencies and percentages in the case of qualitative variables. In the second place, the psychometric properties of the scale were analyzed:

- Distribution of the scores and feasibility of the scale. Descriptive statistics of each item and total score (mean, standard deviation- [SD], median, minimum and maximum value and kurtosis coefficient), percentage of no response and time needed to fill out the CUDOS scale (trimmed mean at 5%) were calculated. Together with this, the ceiling effect (percentage of patients with maximum effect) and floor effect (percentage of patients with minimum score) were verified.
- Differential item functioning (DIF). The existence of bias in the scores, based on the patients' gender, was analyzed first. To do so, the Mantel-Haenszel statistics was calculated. This index expresses the ratio or coefficient between the likelihood of having a low versus a high score in each item in the group of men and the likelihood of scoring low versus high in the group of women. Statistical values other than 1 would be indicators of non-uniform DIF (likelihood of scoring high or low in depression would be greater in women or in men).
- Internal consistency, capacity of discrimination of the items and construct validity. In terms of reliability, Alpha's Cronbach was calculated as indicator of internal consistency and capacity of discrimination of the items making up the scale was calculated with the corrected

Table 2 Score in the means of symptomatic severity and affectation of the health-related quality of life of the patients

	N	Minimum	Maximum	Mean	SD
HAMD-17	305	3	43	16.75	7.32
SOFAS scale	305	0	90	62.53	16.77
Standardized Physical Summary component (PCS)	304	21.45	63.59	44.05	9.12
Standardized mental component summary (MCS)	304	2.64	58.19	28.02	9.94
Number of previous episodes	126	1	30	2.80	3.70
Charlson comorbidity index	305	0	6	0.57	1.09

Disease Severity	CGI-SI (n=305)		PGI-SI (n=304)	
	Frequency	Percentage	Frequency	Percentage
Not evaluated	0	0.0	3	1.0
Normal	2	0.7	14	4.6
Doubtfully ill	9	3.0	21	6.9
Mildly ill	75	24.6	63	20.7
Moderately ill	137	44.9	101	33.1
Very ill	74	24.3	74	24.3
Severely ill	5	1.6	23	7.5
Among the most extremely ill patients	3	1.0	5	1.6

item-total correlation. Finally, the Principal Component Analysis (CPA) was applied in order to provide evidence on the internal structure of the CUDOS scale, described in the original work as unidimensional.[27]

- Discriminant and criterion validity. The differences on the CUDOS scores were evaluated on the CUDOS scale based on severity, sociodemographic variables, PRIME-MD classification and risk factors. Symptomatic severity was defined in accordance with the HAMD-17 and CGI-S and PGI-S scales. The differences were constructed with the ANOVA test (Scheffe contrast) in case of parametric distributions and Kruskal-Wallis and Mann-Whitney distributions with Bonferroni corrections 2 by 2 as non-parametric tests.
- Convergent validity: Pearson's correlation between the CUDOS and HAMD-17 scales was analyzed. The relationship of the CUDOS scale with the SF-36 questionnaire (PCS and MCS) and the SOFAS scale was verified with the same statistics.

Finally, a multivariate regression analysis (successive steps method with entry criterion of 0.05 and exit of 0.1) was applied, considering the score on the CUDOS scale as dependent variable. The scores with the HAMD-17, SF-36, SOFAS instruments together with age, Charlson comorbidity index and risk factors were contrasted as independent variables (controlling effect of gender of the patients as possible modulator variable).

In all the statistical tests, 0.05 level of statistical significance was used. The software used in the analyses were STATA v.10 and SPSS (16.0).

RESULTS

Stage I: Linguistic adaptation

All of the items of the initial version of CUDOS were positively evaluated in importance and comprehensibility by the experts (figure 2). On the other hand, discrepancies were found in the case of the patients, fundamentally regarding the importance of some item. However, it should be stated that these items were maintained since they did not entail comprehension problems and the experts consider them to be very important. It merits mention that four statements were discussed and slightly modified during the session that presented the results to improve their understandability. Generally, there was no concordance between the scores given by the groups participating in this process (intraclass correlation coefficients <0.35; p>0.5).

Table 3 Characteristics of the items of the CUDOS scale and their total score

	% Floor E.	% Ceiling E.	% Not valid	mean	SD	Median	Min	Max	g_2	DI	[a]DIF
Total CUDOS (Items 1-16)	0.35	0.00	6.56	29.86	12.12	29.00	0.00	58.00	-0.42	------	1.31
Item 1	1.64	30.82	0.00	2.69	1.09	3.00	0.00	4.00	-0.94	0.64	0.91
Item 2	4.93	29.93	0.33	2.64	1.19	3.00	0.00	4.00	-0.73	0.66	1.15
Item 3	30.13	18.21	0.98	1.76	1.48	2.00	0.00	4.00	-1.35	0.41	1.08
Item 4	57.33	8.33	1.64	0.91	1.30	0.00	0.00	4.00	0.32	0.21	1.41
Item 5	11.80	35.74	0.00	2.61	1.37	3.00	0.00	4.00	-0.84	0.47	1.25
Item 6	61.13	6.98	1.31	0.77	1.21	0.00	0.00	4.00	1.32	0.15	0.92
Item 7	11.88	16.17	0.66	2.14	1.23	2.00	0.00	4.00	-0.89	0.47	1.10
Item 8	8.88	21.38	0.33	2.37	1.22	2.00	0.00	4.00	-0.79	0.50	0.92
Item 9	5.59	29.93	0.33	2.69	1.16	3.00	0.00	4.00	-0.41	0.63	1.45
Item 10	25.00	21.05	0.33	1.93	1.49	2.00	0.00	4.00	-1.42	0.65	0.99
Item 11	30.49	17.70	0.00	1.72	1.49	2.00	0.00	4.00	-1.36	0.67	1.30
Item 12	6.58	18.75	0.33	2.37	1.14	2.00	0.00	4.00	-0.62	0.64	1.29
Item 13	9.24	14.52	0.66	2.15	1.16	2.00	0.00	4.00	-0.67	0.64	0.82
Item 14	61.51	8.55	0.33	0.89	1.33	0.00	0.00	4.00	0.24	0.60	1.10
Item 15	79.67	3.28	0.00	0.42	0.96	0.00	0.00	4.00	5.13	0.48	0.69
Item 16	27.63	14.80	0.33	1.64	1.40	1.00	0.00	4.00	-1.14	0.63	1.20
Item 17	3.72	17.57	2.95	2.49	1.09	3.00	0.00	4.00	-0.64	------	1.12
Item 18	0.00	8.30	5.25	2.51	0.77	3.00	1.00	4.00	-0.36	------	1.32

g_2: Kurtosis; DI: Discrimination Index of the item (corrected item-total correlation); DIF: Differential item functioning based on the variable gender (Mantel-Haenszel test). [a]The DIF was not statistically significant in any of the contrasts proposed (DIF: p≥0.2).

The final version of the CUDOS scale to be validated in the second stage of the study is shown in the Annex.

Stage II. Analysis of the psychometric properties of the adapted CUDOS version

Profile of the MDD patients evaluated

The final sample included 305 patients (69.5% women) with a mean age (SD) of 51.75 (15.53) years. The socio-demographic and clinical descriptive variables are shown in tables 1 and 2. A total of 87.5% of the patients were receiving antidepressant treatment and 15.4% of the patients had MDD with partial remission according to the PRIME-MD classification. In accordance with the severity classification used in the HAMD-17, 7.9% of the patients did not have depressive symptoms (0-7 points), 29.8% had minor depression (8-13 points), 22.0% moderate depression (14-18 points), 21% severe depression (19-22) and 19.3%, very severe depression (≥23 points).

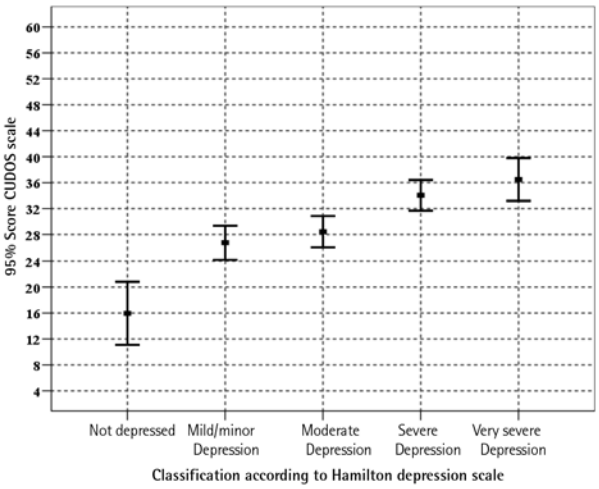
Feasibility of the CUDOS scale and distribution of the scores:

Mean time to fill out the scale (Trimmed at 5%) was 4.47 (±2.40) minutes. On the other hand, the percentage of no response for items 1-16 was less than 3%, it being possible to obtain the total score in 93.44% of the patients (table 3). In the sample evaluated, no patients with the maximum score were found and 0.35% of them had the minimum score. Regarding distribution of the scores, the Kurtosis coefficient (g_2), asymmetry statistics (-0,07) and standard error (0.14) were, in this case, indicators of a symmetric distribution of the scores in the study sample, which also adjusted to a normal curve (Kolmogorov-Smirnov Z= 0.84; p=0.48).

Differential functioning of the items

Table 3 shows the Mantel-Haenszel values. A non-uniform DIF that was statistically significant was not found in any item, this indicating that men and women had a similar likelihood of indicating high or low scores in each score analyzed.

Table 4	Principal Components Analysis (PCA): variance explained and matrix of components			
	PCA items 1-16		PCA eliminating items 4 and 6	
Components	Total	% of the variance	Total	% of the variance
1	6.11	38.19	6.03	43.10
2	1.80	11.27	1.77	12.67
3	1.5	9.81	1.04	7.41
4	1.057	6.61	0.92	6.54
Matrix of components				
Items		Component 1		Component 1
1		0.724		0.733
2		0.745		0.750
3		0.521		0.538
4		0.236		-----
5		0.548		0.545
6		0.168		-----
7		0.541		0.531
8		0.571		0.574
9		0.697		0.699
10		0.702		0.696
11		0.726		0.720
12		0.722		0.724
13		0.719		0.722
14		0.662		0.664
15		0.536		0.531
16		0.698		0.689
Correlation between components 1 and 2		0.450		0.453
Cronbach α		0.878		0.893



Classification according to Hamilton depression scale
Among the not depressed/mild-moderate depression/severe-very severe depression: Chi^2 =54.165; p<0.001 (Kruskal-Wallis). Bonferroni Contrast p<0.03 in all the tests 2to2

Figure 3 — *Differences of means on the CUDOS scale based on severity of the depression (Hamilton depression scale)*

Reliability and construct validity

The indicators of internal consistency of the CUDOS scale reflected adequate levels in this criterion (table 4). Regarding the discrimination index (DI), the values of all the items were greater than 0.4 with 2 exceptions: "I was sleeping too much" and "my appetite was much greater than usual." These seem to have very low discrimination power, at least in the sample evaluated (table 3).

In the principal component analysis (PCA) carried out with the 16 summary scoring items (table 4), sampling adequacy for the analysis (Kaiser-Meyer-Oklin=0.86, p<0.001) was contrasted first. After, the sedimentation chart (figure not shown) reflected the existence of a first dominant component (self-value=6.11) that accounted for 38.2% of the total variance versus 11.3%, 9.8% and 6.6% of the rest of the components with self-values greater than 1. After applying the rotation (Oblimin with Kaiser Normalization), it could be verified in the configuration matrix that 6 items had significant weights (>0.3) in multiple components. These items would also refer to differentiated contents (items 1, 3, 6-7, 10-11) and the matrical solution would be difficult to interpret. Consequently, analysis for extraction of the 2 principal components (which would explain about 50% of the variance) with ortogonal rotation was forced, but the correlation between these 2 components was important (0.45) and 7 questions had significant weights in both factors (items: 5, 7, 10-13, 16), also generating interpretation problems. Extraction of a single component from these data was performed, observing that all the items of the scale had a moderate-high correlation with it (with the exception of questions 4 and 6). Because the elimination of the items on the scale with low discrimination capacity should be proposed, the internal consistency indexes and the PCA were recalculated (table 4). It should be stated that when the residual correlation matrix (between observed and reproduced) was analyzed, a multidimensional solution that was clearly superior in the percentage of non-redundant

Table 5 Discriminant validy of CUDOS scale

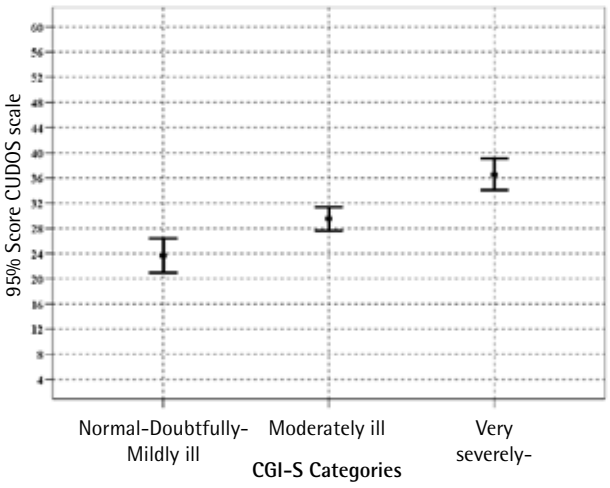
Variables		Score CUDOS scale				
		N	Mean	SD	TME	*p
Gender	Male	87	29.03	11.87	1.27	0.482
	Female	198	30.22	12.24	0.87	
Cohabitation	Alone	34	29.74	13.52	2.32	0.837
	Accompanied or in family	250	29.91	11.96	0.76	
Age	<40 years	67	29.58	12.62	1.54	0.150
	40-65 years	157	30.92	12.24	0.98	
	>65 years	61	27.43	11.04	1.41	
Training	None / basic	135	29.76	12.44	1.07	0.519
	Upper	56	27.84	11.95	1.60	
Result on PRIME-MD scale	MDD symptoms	243	30.79	11.80	0.76	0.003
	Partial remission	42	24.48	12.70	1.96	
Previous depressive episodes	Yes	121	31.01	12.23	1.11	0.228
	No	164	29.01	12.01	0.94	
Background of familial depression	Yes	110	31.85	10.88	1.04	0.022
	No	152	28.29	13.21	1.07	
Severe problems of close persons	Yes	85	33.61	11.19	1.21	0.001
	No	191	28.26	12.40	0.90	
Financial or work problems	Yes	113	32.50	11.68	1.10	0.002
	No	172	28.12	12.13	0.92	
Problems of cohabitation /family	Yes	87	35.09	11.06	1.19	0.001
	No	196	27.55	11.91	0.85	

* Mann-Whitney Test

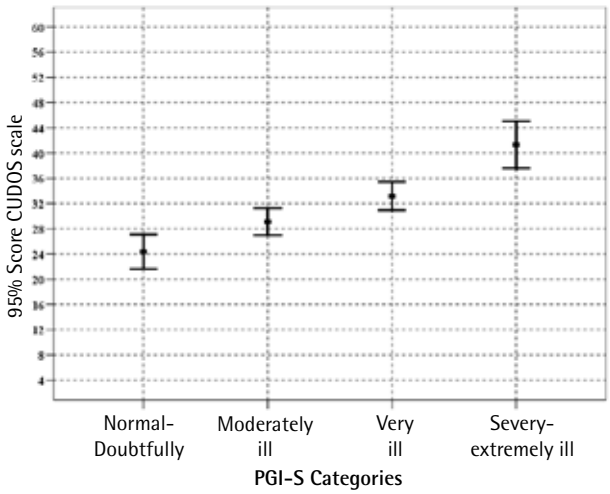
Table 6 Correlation between scores on CUDOS scale, SF-36 and SOFAS scale of social functioning of the patient

	SF-36: PCS	SF-36: MCS	CUDOS Scale	SOFAS Scale
SF-36: MCS	-0.074			
CUDOS Scale	-0.224(**)	-0.650(**)		
SOFAS Scale	0.351(**)	0.368(**)	-0.423(**)	
Item 17 CUDOS	-0.219(**)	-0.588(**)	0.645(**)	-0.456(**)
Item 18 CUDOS	-0.145(*)	-0.559(**)	0.604(**)	-0.464(**)

** The correlation is significant at level 0.01 (bilateral)



$F_{2,284}$= 25.447; p<0.001. Scheffé Contrast p<0.002 in all the tests 2 to 2.



Chi^2= 47.208; p<0.001 (Kruskal-Wallis). Bonferroni Contrast p<0.05 in all the tests 2 to 2

Figure 4 — *Score on CUDOS scale based on Clinical Global Impression Scale (CGI-S) and Patient Global Impression for Severity (PGI-S)*

residuals versus the unidimensional was not clear in any case.

Criterion and discriminant validity

To evaluate these properties, the differences in the scores on the CUDOS scale based on different criteria were contrasted. In relation to the classification of severity of the HAMD-17, the CUDOS scale discriminated between three categories: not depressed / mild-moderate depression / severe-very severe depression (p<0.03 with Bonferroni correction; figure 3). Significant differences were also found in the scores on the CUDOS scale in relation to the categories defined on the CGI-S and PGI-S scales (p<0.002 and p<0.05; figure 4). In addition to these evidences, table 5 shows additional contrasts, considering socio-demographic variables and those regarding personal situations that could constitute a risk factor for the appearance or maintenance of depressive disorders.

Convergent validity

Pearson's correlation coefficient for CUDOS and the HAMD-17 scale was moderate, positive and significant (r=0.451; p<0.001). Together with this, the total score on the CUDOS scale (items 1-16) and the questions regarding degree of interference in the life of the patients and the general HRQL (items 17 and 18, respectively) moderately and significantly associated the mental component score of the SF-36 (MCS) and the SOFAS scale (table 6).

Factors associated to the CUDOS score

The independent variables included in the multivariate model would explain 50% of the differences in the scores on the CUDOS scale (R^2=0.495. $F_{3,252}$= 82.34; p<0.001). The relative weights of each variable included in the final model were the following (standardized coefficients): MCS (ß=-0.526; p<0.001), HAMD-17 (ß=0.260; p<0.001) and cohabitation problems (ß=-0.121; p=0.01). Finally, it should be stated that none of these variables in the final model presented any problem of colinearity, after analyzing the indexes of the condition and proportions of the variance.

DISCUSSION

The present study aimed to perform a cultural adaptation and analysis of the psychometric properties of the CUDOS scale, a brief self-applied instrument whose original version was shown to be useful in the clinical practice for efficient evaluation of patients with depression.[26-29,43]

Although the Hamilton and Montgomery-Åsberg depression scales are those used most frequently for the clinical evaluation of patients with MDD,[35,44] they have been designed to collect information strictly from the clinical

point of view. As has already been indicated, the perspective of the patients is an essential component to identify relevant symptoms and to evaluate how they affect their daily life.[13,15,22,25] Among others, examples of self-applied instruments available in our country are the widely used Beck Depression Inventory (BDI),[45] PHQ-15[46] (focused on somatic symptoms associated to depression and anxiety) and the method based on visual analogue scales, successfully used in outpatients evaluated in a mental health center.[47] Compared to these most recent ones, the CUDOS scale offers a more complete description of the symptoms associated to MDD in accordance with the DSM-IV and also makes it possible to evaluate other important aspects such as the functional capacity of the patient and their involvement in the health-related quality of life.

Regarding the feasibility of use of the scale, mean time to complete the adapted version (4.5 minutes, SD=2.4) was greater than that indicated by the authors of the original version (3 minutes).[29] Even so, this was a reasonable time within the context of PC.

In regards to its internal structure, the results of the PCA along with the internal consistency and discrimination indexes make it possible to assume its unidimensionality. However, some of its limitations should be considered. Among others, although the CUDOS scale (items 1-16) has high internal consistency with values similar to those previously published in the original version[27] (Cronbach α of 0.88 and 0.9, respectively), items 4 and 6 should be analyzed again in subsequent works in order to evaluate their possible elimination, at least in the calculation of the score on the CUDOS scale.

In spite of the above, the criterion and discriminant validity of the CUDOS scale were confirmed. This was first confirmed by the differences in means found between three categories according to the HAMD-17: not depressed / mild/ minor depression/ moderate depression / severe - very severe depression. The differences in accordance to the different severity measurements of affectation or symptoms (CGI-S and PRIME-MD) were also contrasted as statistically significance. In addition to this, the convergent validity of the version we present seems reasonable: their scores were significant and moderately associated with the Hamilton scale (0.45 in the Spanish version and 0.69 in the original; both $p<0.001$). Based on these differences in the HAMD-17, the scores on the CUDOS scale for MDD patients could be grouped around 3 clusters: 0-24-not depressed / 24-32-mild or moderate depression / >32: severe or very severe depression. This first approach, different from that provided by the original authors, should be analyzed in detail in future studies with different samples and groups in order to better clarify the scales. We understand that the same can be applied to the differential functioning of the items and scales. Although it could be determined that bias was not produced by DIF in relation to gender, these analyses (or other more complete ones, although less intuitive such as the Logit or Rasch analysis) regarding new contexts and variables need to be performed.

Finally, in the multivariate regression model, the independent variables that were significantly associated to the CUDOS score were the mental component of SF-36 (MCS), HAMD-17 and cohabitation problems of the patients. These results agree with those published recently in our country, also in PC.[40]

Within the limitations of this study, we should indicate that the information presented comes from a single evaluation visit, without follow-up, so that information could not be presented on the sensitivity to detect clinically significant changes in the patients' situation.[48] It should also be said that the population analyzed corresponds to PC patients and the scores could be different for very severe and chronic patients such as those attended in specialized care.

In conclusion, the Spanish version of the CUDOS scale has adequate reliability and descriptive and discriminate performance. Furthermore, it is easily filled out by the patients. These facts, together with the possibility of obtaining summary scores rapidly, facilitate its use in the evaluation of MDD during the clinical practice in Primary Care.

CONFLICT OF INTERESTS

This study was funded by the Medical Department of AstraZeneca España. E.M and J.M are employees of AstraZeneca España. J.C and H.D-C are employees of BAP LA-SER Outcomes España. L.A and C.M have no conflicts of interest to declare.

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ANNEX I | **Version in Spanish of the CUDOS scale (Clinically Useful Depression Outcome Scale)**

Durante la SEMANA PASADA, INCLUYENDO HOY.....	No es cierto en absoluto (0 días)	Rara vez cierto (1-2 días)	A veces cierto (3-4 días)	A menudo cierto (5-6 días)	Casi siempre cierto (cada día)
1. Me he sentido triste o deprimido	0	1	2	3	4
2. He perdido interés en mis actividades cotidianas	0	1	2	3	4
3. He tenido poco apetito y no me apetecía comer	0	1	2	3	4
4. He tenido mucho más apetito de lo habitual	0	1	2	3	4
5. He tenido dificultades para dormir	0	1	2	3	4
6. He dormido demasiado	0	1	2	3	4
7. Me he sentido muy nervioso, resultándome difícil permanecer quieto	0	1	2	3	4
8. Me he sentido físicamente más lento o pesado	0	1	2	3	4
9. He tenido poca energía	0	1	2	3	4
10. Me he sentido culpable	0	1	2	3	4
11. He pensado que era un fracasado	0	1	2	3	4
12. He tenido problemas de concentración	0	1	2	3	4
13. He tenido más problemas para tomar decisiones que habitualmente	0	1	2	3	4
14. He deseado estar muerto	0	1	2	3	4
15. He pensado en suicidarme	0	1	2	3	4
16. He pensado que no había esperanza en el futuro	0	1	2	3	4

17. En general, ¿en qué medida los síntomas de depresión han interferido o le han causado problemas en su vida diaria durante la semana pasada?

0: Nada	1: Un poco	2: Moderadamente	3: Bastante	4: Mucho

18. Durante la semana pasada, ¿cómo calificaría su calidad de vida en general?

0: Muy buena, mi vida no podría ser mejor	1: Bastante buena, la mayoría de mis cosas están yendo bien	2: Las partes buenas y malas están más o menos igualadas	3: Bastante mala, la mayoría de mis cosas están yendo mal	4: Muy mala, mi vida no podría ser peor

(CONSULT FOR VERSION IN ENGLISH https://outcometracker.org/CUDOS.pdf)