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Validation of the Spanish Version of the PHQ-15 Questionnaire for the evaluation of physical symptoms in patients with depression and/or anxiety disorders: DEPRE-SOMA study

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Objective. This work has aimed to validate the Spanish version of the PHQ-15 questionnaire (Patient Health Questionnaire) for its use in patients with depression and/or and anxiety disorders.

Material and methods. An observational, cross-sectional study in which the PHQ-15 questionnaire (made up of 15 items on somatic symptoms) was administered in the outpatient psychiatric clinics to patients of 18 years or more, diagnosed of depression and/or anxiety disorder according to the DSM-IV criteria. Feasibility (percent of patients without response), reliability (in terms of internal consistency) and convergent/divergent validity compared to the MADRS scale (by correlational analysis), discriminant (with intra-group comparison) and predictive (by logistical regression).

Results. A total of 3362 evaluated patients were included. Of these, 65.5% were women, with a mean age of 45.6 years (18.0-90.0). The questionnaire was feasible (9.6% of patients lacking an answer to some item), and showed acceptable internal reliability (Cronbach's Alpha Coefficient =0.78) with adequate validity, with correlations with the MADRS scale between moderate and high (r=0.3-0.7) and differences between groups of patients. The factors associated to the profile type of the patient with relevant physical symptoms were: being a woman, having a background of depression and/or anxiety, anxiety according to the DSM-IV, any concomitant condition in general, and specifically hepatic-digestive and osteoarticular system affectation and, as protective factor, being 70 years of age or older.

Conclusion. The PHQ-15 questionnaire in its Spanish version has been shown to be feasible, reliable and valid to evaluate somatic symptoms in patients with depression and/or anxiety disorders in psychiatry.

Keywords:
Validation, PHQ-15 questionnaire, depression, anxiety, somatization.

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Validación de la Versión Española del Cuestionario PHQ-15 para la evaluación de síntomas físicos en pacientes con trastornos de depresión y/o ansiedad: estudio DEPRE-SOMA

Objetivo. El objetivo de este trabajo fue validar la versión española del cuestionario PHQ-15 (Patient Health Questionnaire) para su uso en pacientes con trastornos de depresión y/o ansiedad.

Material y métodos. Estudio observacional transversal, en que el cuestionario PHQ-15 (compuesto por 15 ítems referentes a síntomas somáticos), fue administrado en Consultas de Psiquiatría a pacientes ambulatorios, de 18 o más años de edad, con diagnóstico de trastorno de depresión y/o ansiedad según criterios DSM-IV. Se evaluó la factibilidad (% de pacientes sin respuesta), fiabilidad (en términos de consistencia interna), y validez convergente/divergente frente a escala MADRS (mediante análisis correlacionales), discriminante (comparando entre grupos) y predictiva (mediante regresión logística).

Resultados. Se incluyeron 3362 pacientes valorables, el 65,5% mujeres, y con una edad media de 45,6 años

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(18,0-90,0). El cuestionario resultó factible (9,6% de pacientes sin respuesta a algún item), y mostró aceptable fiabilidad interna (Coeficiente Alfa de Cronbach=0,78) y adecuada validez, con correlaciones con escala MADRS entre moderadas y altas (r=0,3-0,7) y diferencias entre grupos de pacientes. Los factores asociados al perfil tipo del paciente con síntomas físicos relevantes fueron: ser mujer, tener antecedentes de depresión y/o ansiedad, ansiedad según DSM-IV, algún diagnóstico psiquiátrico concomitante, alguna patología concomitante en general, y en particular patología hepático-digestiva y del sistema osteoarticular, y, como factor protector, tener 70 o más años de edad.

Conclusión. El cuestionario PHQ-15 en su versión española se mostró factible, fiable y válido para evaluar síntomas somáticos en pacientes con trastornos de depresión y/o ansiedad en Psiquiatría.

Palabras clave:
Validación, cuestionario PHQ-15, depresión; ansiedad; somatización.

INTRODUCTION

Previous studies have shown that 3 out of every 4 patients with depression have physical symptoms such as pain, breathing problems, fatigue, nausea and anorexia.[1] Specifically, the prevalence of depression with physical symptoms is much higher in women and is associated to anxiety and chronic dysphoria disorders.[2] Additionally, it has been described that such somatization associated to depression may even appear associated, in turn, to a higher degree of utilization of diagnostic tests such as colonoscopies or cytologies,[3] with their corresponding additional cost. However, the role of the somatic symptoms in patients with depression and/or anxiety has been historically underestimated and little recognized.[4] The prevalence of the somatic manifestations has varied historically and continue to vary among populations and countries, both in regards to prevalence of the depression and/or anxiety disorders[5] as well as in reference to the preference of associated physical symptoms and somatization of depression and/or anxiety disorders per se.[6-8] Different adequately validated psychiatric scales have been used for the clinical evaluation of the depression and anxiety symptoms in the research studies, which has made it possible to quantify depressive and anxious symptoms. However, the availability of measurement instruments to be able to identify and evaluate somatic symptoms is much more limited. Specifically, different measurements have been developed for the detection and evaluation of symptoms in general, such as the SCL-90 scales,[9] or SUNYA psychosomatic checklist,[10] which evaluate many somatic symptoms. However, these measurements have a series of general limitations such as being too long or because they have not been specifically validated to evaluate somatic symptoms in psychiatric patients as well as in the general population. Another limitation of the measurements available to evaluate somatic symptoms associated to depression and/or anxiety in psychiatry is that none of them specifically evaluate the eating behavior disorders that have generally been described as frequently occurring in these patients, such as recurrent episodes of binge eating, self-induced vomiting or alterations in the perception of body shape and weight. Only a few of the already existing psychiatric scales for the evaluation of symptoms of depression and/or anxiety such as the HDRS (Hamilton Depression Rating Scale) consider aspects regarding eating behavior such as weight loss or somatizations in the gastrointestinal tract that may lead to appetite loss. In this context, the PHQ-15 questionnaire (Patient Health Questionnaire-15) is a version of the PRIME-MD diagnostic instrument for common mental disorders, that is made up of 15 somatic symptoms. This questionnaire has been used in many studies[11-13] to determine severity of the somatic symptoms and has been validated in other previous studies.[7,14] The purpose of this present study has been to validate the PHQ-15 questionnaire in its Spanish version as a tool to evaluate somatic symptoms associated to depression and/or anxiety disorders.

MATERIAL AND METHODS

Study design

This is an observational, multicenter, cross-sectional study with a single group of patients and with a single baseline or enrollment visit of the patients for the study.

Investigators and patients

The study was conducted between March and July 2005 in the Psychiatric Medical Clinics throughout the entire Spanish geographic area. Outpatients, 18 years or older, diagnosed with depression and/or anxiety according to the DSM-IV criteria, were selected for the study.

The study was conducted within the usual clinical practice conditions. In relationship to the possible treatments that the patients could be receiving, and although this was an observational study that was not performed with medications, which had a naturalistic and cross-sectional design, in agreement with the recommendations of the Spanish healthcare authorities (Agencia Española de Medicamentos y Productos Sanitarios) on post-authorization studies in force,[15] it was established that each investigator would be free to prescribe, change or continue any treatment

which, in accordance with his/her clinical opinion, was required. During the development of the study, the anonymity of the patient's personal data was guaranteed at all times, so that the case report forms did not contain any information that could allow for his/her identification.

Description of the PHQ-15 Questionnaire

The PHQ-15 health care questionnaire[14] is made up of 15 items regarding 15 possible physical problems that may have bothered the patients over the last 4 weeks (See Annex 1): stomach pain, back pain, pain in your arms, legs, or joints, menstrual cramps, headaches, thoracic pain (chest), dizziness, fainting spells or feeling your heart pound or race, shortness of breath, pain or problems during sexual intercourse, constipation/diarrhea, nauseas/gas or indigestion, feeling tired or having low energy and sleep problems. The possible options of response to each one of the 15 items are: "not bothered," or absence of physical problem (0 points), "a little" or presence of the problem (1 point), or "a lot" or much presence of the problem (2 points). A global score is obtained based on the sum of the scores of the 15 items, with a range going from 0 to 30 points. After, the patients are classified into two groups for the regression analysis: patients without important physical symptoms (from 0 to 4 points) and patients with important physical symptoms (>4 points).

Data collection and description of other measurements

In order to be able to evaluate the depression and anxiety symptoms of the patients, the answers made to the Montgomery-Asberg Depression Rating Scale (MADRS)[16] were analyzed. The MADRS scale was made up of 10 possible depression symptoms that could have affected the patient. These were observed sadness, sadness declared by the patient, internal tension, reduced sleep, reduced appetite, decreased concentration, decreased energy, incapacity to feel, pessimistic thoughts and suicidal thoughts. Each depression symptom represented one item on the questionnaire. The value of these items ranged from 0 minimum severity) to 6 (maximum severity) points based on the degree of affect they had on the patient's depression symptom. The global score of the MADRS questionnaire was obtained from the sum of the scores of the 10 items, this score ranging from 0 to 60 points. If one of the items was not answered, the global score of the scale could not be calculated for the patient in question.

The secondary variables included data collected on the different characteristics of the biosociodemographic and clinical profile of the patients in order to be able to describe the patient's profile and study their association with the presence of physical symptoms and to evaluate the possible predictive validity of the PHQ-15 questionnaire.

Statistical analysis

Once the study data had been tabulated and the quality control performed, the results were analyzed using the SPSS statistical program, version 13.0.

A single sample was analyzed, including all the patients who met the selection criteria. In the descriptive analyses for the quantitative variables, the calculation of the mean, standard deviation and range was used and for the qualitative variables, frequencies and percentages were used.

To evaluate the feasibility of the questionnaire, the percentage of patients for which there was no response for each one of the items on the questionnaire and for the total of the questionnaire was calculated. In addition, the distribution of the total scores obtained with this questionnaire was studied. To do so, the percentage of patients with each one of the different possible total scores was calculated.

Reliability was analyzed in terms of internal consistency with Cronbach's Alpha Coefficient for the total of the scale.

Three types of analyses were carried out to evaluate validity. In the first place, to evaluate convergence/divergence of validity, correlational analyses were made between the scores obtained on the questionnaire and those obtained on different items on the MADRS scale with the Spearman correlation coefficient. In the second place, statistical tests to compare non-parametric groups (Mann-Whitney-Wilcoxon and Kruskall-Wallis) were used in order to evaluate the discriminant validity understood as the capacity of the scale to discriminate between subgroups of patients according to different biosociodemographic characteristics, DSM-IV diagnoses, background of depression and/or anxiety, concomitant diagnoses and concomitant conditions. Finally, to evaluate predictive validity, logistic regression analysis methods were used. These methods studied the possible factors associated to the presence of physical symptoms according to the score on the PHQ-15 questionnaire being studied, in which the following variables were initially introduced as possible factors: gender (man/woman); age (less than 30 years/between 30 and 49 / 50 and 69 / and 70 years or more); BMI (low weight, <18.5)/normal weight, ≥18.5 – <25) / overweight, ≥25 – <30 / mild obesity, ≥30 – <40 / morbid obesity, ≥40); living condition (alone/accompanied); home site (rural/urban zone); level of studies (incomplete primary education or no studies / complete primary education/complete secondary education/complete university studies); background of depression and/or anxiety

(with/without backgrounds); diagnoses of depression and/or anxiety disorder according to the DSM-IV (depression/anxiety/depression and anxiety); concomitant psychiatric diagnoses (with/without concomitant diagnosis); presence of concomitant conditions (with/without concomitant condition); and involvement of the nervous system, cardiovascular, respiratory, endocrine, and hepatic-digestive system, osteoarticular, or urological (with/without affectations, respectively).

The referenced p values in this manuscript correspond to the statistical significance of the two-tailed tests. Values under or equal to 0.05 were considered statistically significant.

RESULTS

Evaluable patients

As described in the study chart (Figure 1), of the 3471 patients enrolled by the 1157 participating investigator physicians, 3362 patients (96.9%) were evaluable for the analysis because 109 patients (3.1%) were excluded for reasons shown in figure 1.

Patient profile

Table 1 provides a description of the biosociodemographic characteristics of the patients, 65.5% of whom were women with a mean age of 45.6 years (SD=13.7). The mean BMI was 25.0 kg/m^2 (SD=3.7) within the normal range. They were predominantly classified as living with a significant other or being married (57.3%), living in urban zone (76.3%) and being accompanied (81.9%), they had completed primary or higher level studies (74.2%), and approximately half were working (51.2%).

In Table 2 describes the anxiety and/or depression disorder characteristics of the patients. All of the patients had some depression and/or anxiety disorder. Specifically, 88.7% of the patients had some depression disorder (n=2981) and 57.3% some anxiety disorder (n=1927). Half of them were receiving only drug treatment (52.1%) for their depression and/or anxiety symptoms or some drug treatment combined with other non-pharmacological treatments (38.4%).

Feasibility and distribution of the scores

In regards to the feasibility of the scale, the PHQ-15 questionnaire was completely answered by most of the patients evaluated (90.4%), although 9.6% of the patients (n=24) did not respond to some of the 15 items on the questionnaire and 0.4% (n=12) did not answer any of the items on the questionnaire.

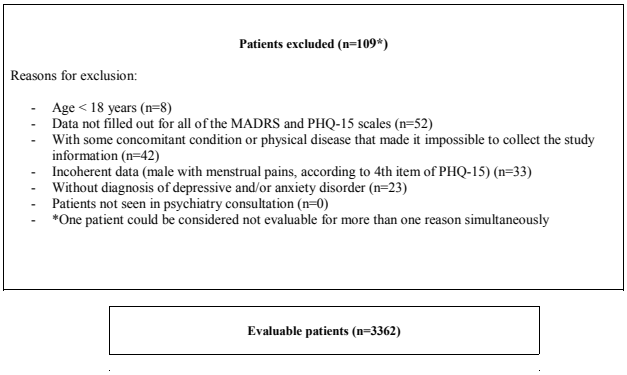

Figure 1 Patient Chart

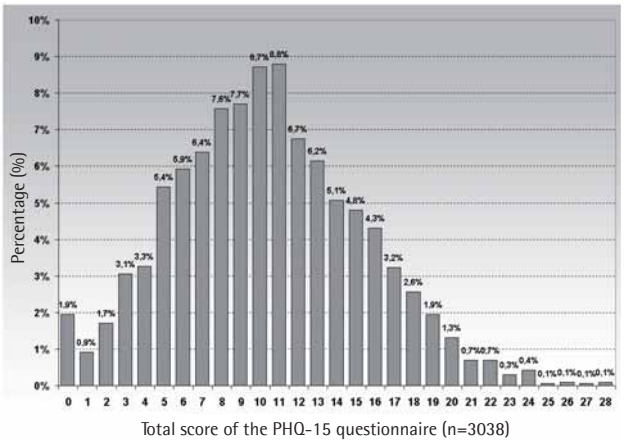

Figura 2 Distribución de la puntuación global del cuestionario PHQ-15

The mean global score of the PHQ-15 patient health questionnaire was 10.4 points (SD: 4.9, range of 0-28). As described in Table 3, the most prevalent physical symptoms in the study were: feeling tired or having low energy (84.4-86.7%), trouble sleeping (81.2-83.8%) and headache (73.1-76.1%). In table 3, the percentages of subjects with minimum score ("floor effect") and maximum score ("ceiling effect") are also described for each one of the items and the total scores of the questionnaire. As can be observed in the table, the "floor effect" was observed in the total score in 59 patients (1.9%) (although the "floor effect" was observed in most of the items (items 1-13) in more than 20% of the patients). On the other hand, no "ceiling effect" was observed for the total score on the PHQ-15 questionnaire (0.0 of the patients with maximum score), although for items 2, 3, 5, 9, 14 and 15, it was observed that more than 20% of the patients responded with the maximum possible score. The results regarding the distribution of the scores obtained with the PHQ-15 questionnaire are shown graphically in Figure 2.

Table 1 Biosociodemographic characteristics of the patients

	n	%[1]	
Gender	3,337	100.0	-
Man	1,152	34.5	-
Woman	2,185	65.5	-
	Mean	**SD**	**Range**
Age (years) (n=3288)	45.6	13.7	18.0 - 90.0
Weight (Kg.) (n=3095)	69.3	12.5	35.0 - 182.0
Height (cm) (n=3042)	166.0	7.8	140.0 - 195.0
BMI (Kg/m2) (n=3035)	25.0	3.7	15.2 - 44.9
	n	**%[1]**	
Civil status	3,353	100.0	-
Single	713	21.3	-
With significant other/married	1,922	57.3	-
Widow(er)	264	7.9	-
Separated	354	10.6	-
Divorced	100	3.0	-
Home	3,275	100.0	-
Rural zone	777	23.7	-
Urban zone	2,498	76.3	-
Living	3,141	100.0	-
Accompanied	2.574	81.9	-
Alone	567	18.1	
Level of studies	3,312	100.0	-
Incomplete primary (primary or similar) or without studies	855	25.8	-
Complete primary (primary or similar)	1,000	30.2	-
Complete secondary (vocational training/secondary or similar)	988	29.8	-
Complete university studies	469	14.2	-
Occupation	3,206	100.0	-
Working	1,642	51.2	-
Unemployed	383	11.9	-
Housewife/househusband	766	23.9	-
Retired or pensioner	415	12.9	-

[1]Percentage calculated regarding the total number of patients available for each datum

Reliability

The reliability of the questionnaire was evaluated in terms of internal consistency, obtaining a Cronbach's alpha coefficient of 0.78, which ranged from 0.76 to 0.781 for the analyses by items, excluding each one of the 15 items studied.

Validity

Table 4 shows the results obtained in the correlations between the PHQ-15 questionnaire and the different items on the MADRS scale, observing correlations between moderate and high ($r > 0.03$ and < 0.7) between the global scores of PHQ-15 questionnaire and the MADRS scale and by

Table 2 Characteristics of the anxiety and/or depression disorder of the patients

	n	%[1]	%[2]
Evaluable patients	**3,362**	**100.0**	**-**
Patients with only depression disorder	1,435	42.7	-
Patients with only anxiety disorder	381	11.3	-
Patients with depression and anxiety disorder	1,546	46.0	-
Patients with depression disorder (3)	**2,981**	**88.7**	**100.0**
Major depressive disorder, recurrent	839	25.0	28.1
Dysthymic disorder	777	23.1	26.1
Major depressive disorder, single episode	776	23.1	26.0
Non-specified depressive disorder	628	18.7	21.1
Patients with anxiety disorder (3)	**1,927**	**57.3**	**100.0**
Generalized anxiety disorder	683	20.3	35.4
Non-specified anxiety disorder	311	9.3	16.1
Anxiety disorder without agoraphobia	306	9.1	15.9
Anxiety disorder with agoraphobia	188	5.6	9.8
Substance-induced anxiety disorder	127	3.8	6.6
Acute stress disorder	100	3.0	5.2
Social phobia	99	2.9	5.1
Obsessive-compulsive disorder	97	2.9	5.0
Anxiety disorder due to medical condition	76	2.3	3.9
Post-traumatic stress disorder	73	2.2	3.8
Specific phobia	32	1.0	1.7
Agoraphobia without background of anxiety	9	0.3	0.5
Background of depression and/or anxiety	**3,338**	**100.0**	**-**
De novo (first episode of depression and/or anxiety)	1,483	44.4	-
With previous episodes of depression and/or anxiety	1,855	55.6	-
	Mean	**SD**	**Range**
Age of appearance of first episode (years) (n=1,715)	34.7	13.0	14-78
No. of previous depressive and/or anxiety episodes (n=1,601)	3.9	3.5	1-38
Duration of current episode (weeks) (n=2,811)	12.8	10.2	0-52
Time passed from first visit (weeks)) (n=2,641)	13.8	49.1	0-1.352
	n	**%[1]**	**%[2]**
Treatment for depressive and/or anxiety symptoms			
Without treatment	242	7.2	-
With treatment	3,099	92.2	100.0
Pharmacological	1,750	52.1	56.5
Non-pharmacological	59	1.8	1.9
Pharmacological and non-pharmacological	1,290	38.4	41.6

[1]Percentage calculated regarding the total number of evaluable patients ; [2]Percentage calculated regarding the total number of patients with depressive or anxiety disorder; [3]One patient could have more than one disorder simultaneously

items, between item 14 of the PHQ-15 questionnaire (feeling tired or having low energy) and items 1, 2, 6, 8 and 9 of the MADRS scale (observed sadness, sadness declared by the patient, decreased concentration, incapacity to feel, and

Table 3 Presence of physical symptoms and "floor" and "ceiling" effect in the score of each item on the PHQ-15 questionnaire

Item	Physical symptom[4]	Presence of each symptom	"Floor" effect[1]		"Ceiling" effect[2]	
		%	n	%[3]	n	%[3]
Item 1	Stomach pain	56.7	1,427	47.0	352	11.6
Item 2	Back pain	59.9	1,324	43.6	610	20.1
Item 3	Pain in your arms, legs, or joints (knees, hips, etc.)	55.3	1,473	48.5	637	21.0
Item 4*	Menstrual cramps or other problems with your periods (Women only)	43.9	1,176	60.1	224	11.4
Item 5	Headaches	74.6	841	27.7	759	25.0
Item 6	Thoracic pain (chest area)	46.0	1,769	58.2	308	10.1
Item 7	Dizziness	50.3	1,633	53.8	299	9.8
Item 8	Fainting spells	13.0	2,833	93.3	67	2.2
Item 9	Feeling your heart pound or race	66.8	1,093	36.0	609	20.0
Item 10	Shortness of breath	60.1	1,315	43.3	487	16.0
Item 11	Pain or problems during sexual intercourse	31.6	2,190	72.1	323	10.6
Item 12	Constipation, loose bowels, or diarrhea	44.7	1,815	59.7	361	11.9
Item 13	Nausea, gas, or indigestion	53.1	1,537	50.6	368	12.1
Item 14	Feeling tired or having low energy	85.6	480	15.8	1.576	51.9
Item 15	Trouble sleeping	82.5	582	19.2	1.127	37.1
	In all	**89.1**	**59**	**1.9**	**0**	**0.0**

[1]: "floor" effect:" patients with total minimum possible score (0 points per Item and 0 point for total). [2]: "Ceiling" effect: Patients with total maximum score possible (2 points per Item and 30 points for total). [3]: Percentage calculated on the total of patients who answered all the questionnaire (n=3,038). [4]: Score for each physical symptom on up to what point the patient had problems during the last weeks: "None " (0 points), "A little " (1 points), "Much" (2 points).
* Calculated only with women

pessimistic thoughts); and between item 15 of the PHQ-15 questionnaire (trouble sleeping) and items 4-6 of the MADRS scale (reduced sleep, reduced appetite, decreased concentration).

Regarding the discriminant validity of the PHQ-15 questionnaire, this property was examined by making a comparison between subgroups of patients established according to different biosociodemographic characteristics, DSM-IV diagnosis, backgrounds of depression and/or anxiety, concomitant diagnosis and concomitant conditions. According to the sample in Table 5, statistically significant differences were observed according to gender, age, if the patient lived alone or accompanied, level of studies, backgrounds and current diagnosis of depression and/or anxiety and concomitant conditions (Mann-Whitney U Test and Kruskal-Wallis Tests; $p<0.05$). Specifically, more problems of relevant physical symptoms (that is, higher scores on the PHQ-15 questionnaire) were observed in women, patients aged 30 to 69 years, who lived accompanied, with incomplete primary studies or no studies, with background of depression and/or anxiety, with anxiety diagnosis according to the DSM-IV, and with concomitant conditions, specifically with respiratory, endocrine, digestive system, osteoarticular and urological systems conditions.

In relationship to the predictive validity, and complementing the discriminant validity analyses, a multivariate regression analysis was carried out. The factors that finally remained in the model as significantly associated to the presence of relevant physical symptoms according to the score obtained in the PHQ-15 questionnaire are shown in table 6. The patients who had the greatest likelihood of having "relevant physical symptoms" according to the PHQ-15 questionnaire (score >4 on the PHQ-15), had the associated characteristics of: being a woman, having a background of depression and/or anxiety, having anxiety according to the DSM-IV, but not having any other concomitant psychiatric diagnosis, having concomitant conditions in general, and, in particular, liver-digestive and osteoarticular system affectations, while being 70 years of age or older was shown to be a protective factor.

Table 4 **Convergent/divergent validity: correlations between PHQ-15 questionnaire and MADRS scale**

		ITEM															
PHQ-15 Questionnaire / MADRS Scale		1 (SP)	2 (BP)	3 (ANJ)	4 (MP)*	5 (HA)	6 (TP)	7 (DIZ)	8 (FA)	9 (PAL)	10 (SOB)	11 (SEX)	12 (CON)	13 (NAU)	14 (TIR)	15 (SP)	GS
Item 1 (OS)	Coef.	**0.046**	**0.109**	**0.087**	**-0.048**	**0.099**	0.012	0.019	**-0.042**	0.015	**0.036**	**0.087**	**0.078**	**0.050**	**0.389**	**0.282**	**0.180**
	Sig.	0.010	<0.001	<0.001	0.031	<0.001	0.483	0.293	0.019	0.391	0.039	<0.001	<0.001	0.004	<0.001	<0.001	<0.001
	n	3,215	3,218	3,212	2,022	3,227	3,193	3,203	3,176	3,216	3,215	3,122	3,205	3,197	3,242	3,243	2,961
Item 2 (SD)	Coef.	**0.064**	**0.106**	**0.128**	**-0.077**	**0.128**	0.008	**0.038**	**-0.050**	0.016	**0.045**	**0.085**	**0.071**	**0.066**	**0.420**	**0.278**	**0.198**
	Sig.	<0.001	<0.001	<0.001	0.001	<0.001	0.655	0.030	0.005	0.366	0.011	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	n	3,214	3,217	3,211	2,021	3,226	3,192	3,202	3,175	3,215	3,214	3,121	3,204	3,196	3,241	3,242	2,960
Item 3 (IT)	Coef.	**0.184**	**0.095**	**0.057**	**0.066**	**0.166**	**0.205**	**0.178**	**0.043**	**0.264**	**0.266**	**0.089**	**0.073**	**0.119**	**0.162**	**0.215**	**0.314**
	Sig.	<0.001	<0.001	0.001	0.003	<0.001	<0.001	<0.001	0.017	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	n	3,214	3,217	3,211	2,021	3,226	3,192	3,202	3,175	3,215	3,213	3,121	3,205	3,197	3,240	3,241	2,961
Item 4 (RS)	Coef.	**0.157**	**0.104**	**0.103**	0.029	**0.161**	**0.122**	**0.089**	0.019	**0.144**	**0.142**	**0.145**	**0.114**	**0.121**	**0.257**	**0.584**	**0.331**
	Sig.	<0.001	<0.001	<0.001	0.195	<0.001	<0.001	<0.001	0.277	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	n	3,209	3,212	3,206	2,018	3,221	3,187	3,197	3,170	3,210	3,209	3,117	3,199	3,191	3,236	3,237	2,956
Item 5 (RA)	Coef.	**0.157**	0.022	**0.044**	**0.048**	**0.074**	**0.081**	**0.042**	**0.052**	**0.077**	**0.088**	**0.145**	**0.126**	**0.153**	**0.199**	**0.320**	**0.220**
	Sig.	<0.001	0.210	0.013	0.030	<0.001	<0.001	0.018	0.003	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	n	3,212	3,215	3,209	2,020	3,224	3,190	3,200	3,173	3,213	3,212	3,119	3,202	3,194	3,239	3,240	2,958
Item 6 (DC)	Coef.	**0.113**	**0.113**	**0.073**	0.003	**0.122**	**0.090**	**0.093**	0.007	**0.138**	**0.154**	**0.128**	**0.084**	**0.120**	**0.330**	**0.323**	**0.274**
	Sig.	<0.001	<0.001	<0.001	0.884	<0.001	<0.001	<0.001	0.691	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	n	3,214	3,217	3,211	2,021	3,226	3,193	3,202	3,175	3,215	3,214	3,121	3,204	3,196	3,241	3,242	2,961
Item 7 (L)	Coef.	**0.068**	**0.140**	**0.155**	**-0.045**	**0.079**	**0.050**	**0.052**	0.004	0.030	**0.062**	**0.111**	**0.102**	**0.077**	**0.417**	**0.276**	**0.225**
	Sig.	<0.001	<0.001	<0.001	0.043	<0.001	0.005	0.003	0.803	0.093	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	n	3,206	3,209	3,203	2,018	3,218	3,184	3,194	3,167	3,207	3,206	3,114	3,196	3,188	3,233	3,234	2,953
Item 8 (IF)	Coef.	**0.090**	**0.081**	**0.094**	0.006	**0.103**	**0.061**	0.030	0.003	0.030	**0.078**	**0.138**	**0.074**	**0.101**	**0.380**	**0.296**	**0.212**
	Sig.	<0.001	<0.001	<0.001	0.805	<0.001	0.001	0.088	0.860	0.094	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	n	3,210	3,213	3,207	2,021	3,222	3,188	3,198	3,171	3,211	3,210	3,117	3,200	3,192	3,237	3,238	2,956
Item 9 (PT)	Coef.	**0.125**	**0.070**	**0.082**	0.041	**0.086**	**0.075**	**0.050**	**0.056**	**0.067**	**0.081**	**0.124**	**0.120**	**0.123**	**0.329**	**0.266**	**0.229**
	Sig.	<0.001	<0.001	<0.001	0.062	<0.001	<0.001	0.005	0.002	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	n	3,209	3,212	3,206	2,020	3,221	3,187	3,197	3,170	3,210	3,209	3,116	3,199	3,191	3,236	3,237	2,955
Item 10 (ST)	Coef.	**0.074**	**0.093**	**0.111**	0.008	**0.107**	**0.066**	**0.060**	**0.069**	**0.048**	**0.059**	**0.104**	**0.113**	**0.106**	**0.281**	**0.265**	**0.199**
	Sig.	<0.001	<0.001	<0.001	0.703	<0.001	<0.001	0.001	<0.001	0.006	0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	n	3,207	3,210	3,204	2,021	3,219	3,185	3,195	3,168	3,208	3,207	3,115	3,197	3,189	3,234	3,235	2,954
GS	Coef.	**0.151**	**0.127**	**0.127**	0.003	**0.161**	**0.105**	**0.088**	0.022	**0.110**	**0.136**	**0.170**	**0.140**	**0.148**	**0.456**	**0.447**	**0.335**
	Sig.	<0.001	<0.001	<0.001	0.881	<0.001	<0.001	<0.001	0.221	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	n	3,182	3,185	3,179	2,004	3,194	3,161	3,170	3,143	3,183	3,181	3,092	3,173	3,165	3,208	3,209	2,933

PHQ-15 Questionnaire: SP = stomach pain; BP = back pain; ANJ = arm, legs or joint (knees, hips, etc) pain; MP = menstrual pains or other discomforts associated to menstruation (only women); HA = headache; TP = Thoracic pain (chest area); DIZ = dizziness; FA = fainting; PAL = palpitations or feeling your heart race; SOB = shortness of breath; SEX = pain or problems during sexual intercourse; CON = constipation, loose bowels or diarrhea; NAU = nausea, gas or indigestion; TIR = feeling tired or having low energy; SP = sleep problems. MADRS Scale: OS = Observed sadness; SD = sadness declared by the patient; IT = internal tension; RS = reduced sleep; RA = reduced appetite; DC = decreased concentration; L = lassitude; IF = incapacity to feel; PT = pessimist thoughts; ST = suicidal thoughts. GS = Global score of the questionnaire. Coef.= Correlation coefficient (bivariate). Sig. = Significant level of the Spearman correlation test. n= Number of patients. In bold, the significant correlation coefficients, and in bold and underlines, the significant correlation coefficients >0.3. * Calculated only with women

Table 5 **Disciminant validity: Score of PHQ-15 Questionnaire according to subgroups of interest**

		n[1]	Mean	SD	Min	Max	p*
Gender	Man	1,059	9.2	4.4	0	25	**<0.001**[2]
	Woman	1,958	11.1	5.1	0	28	
Age (years)	Under 30 years	380	10.0	4.8	0	26	**0.010**[3]
	Between 30 and 49 years	1,497	10.6	5.1	0	28	
	Between 50 and 69 years	952	10.6	4.8	0	28	
	70 years and older	143	9.3	4.4	0	20	
BMI (kg/m^2)	Underweight (<18.5)	74	11.6	5.7	0	24	0.072[3]
	Normal weight (≥18.5 – <25)	1,339	10.5	5.0	0	28	
	Overweight (≥25 – <30)	1,106	10.4	4.9	0	28	
	Mild obesity (≥30 – <40)	241	11.0	4.9	0	23	
	Morbid obesity (≥40)	5	12.2	8.8	2	24	
Living	Alone	516	9.9	4.8	0	28	**0.007**[2]
	Accompanied/a	2,341	10.5	4.9	0	28	
Home	Rural zone	713	10.5	4.9	0	28	0.962[2]
	Urban zone	2,259	10.4	4.9	0	28	
Level of studies	Incomplete primary /without studies	737	11.0	4.8	0	28	**<0.001**[3]
	Complete primary	912	10.6	5.0	0	28	
	Complete secondary	915	10.1	4.8	0	26	
	Complete university studies	436	9.8	5.2	0	28	
Backgrounds of depression and/or anxiety	With background	1,671	10.8	4.8	0	28	**<0.001**[2]
	Without background	1,343	10.0	5.0	0	28	
Anxiety and/or depression according to DSM-IV	Depression	1,298	9.7	4.5	0	28	**<0.001**[3]
	Anxiety	353	11.1	4.5	0	23	
	Depression and anxiety	1,387	10.9	5.3	0	28	
Concomitant psychiatric diagnosis	With concomitant diagnosis	738	10.4	5.6	0	28	0.746[2]
	Without concomitant diagnosis	2,300	10.4	4.7	0	28	
Concomitant conditions	With concomitant condition	1,314	11.1	4.7	0	28	**<0.001**[2]
	Without concomitant condition	1,724	9.9	5.1	0	28	
Nervous system condition	With nervous system condition	63	10.9	4.3	2	21	0.369[2]
	Without nervous system condition	2,975	10.4	4.9	0	28	
Cardiovascular disease	With cardiovascular condition	357	10.6	4.7	1	23	0.239[2]
	Without cardiovascular condition	2,681	10.4	5.0	0	28	
Respiratory disease	With respiratory condition	196	11.2	5.0	0	24	**0.024**[2]
	Without respiratory condition	2,842	10.3	4.9	0	28	
Endocrine disease	With endocrine condition	256	11.6	4.9	0	28	**<0.001**[2]
	Without endocrine condition	2,782	10.3	4.9	0	28	
Hepatic-digestive disease	With hepatic-digestive condition	204	12.0	4.4	1	27	**<0.001**[2]
	Without hepatic-digestive condition	2,834	10.3	4.9	0	28	
Osteoarticular condition	With osteoarticular condition	484	12.1	4.4	1	27	**<0.001**[2]
	With osteoarticular condition	2,554	10.1	4.9	0	28	
Urological condition	With urological condition	100	11.6	4.6	2	27	**0.012**[2]
	Without urological condition	2,938	10.4	4.9	0	28	

[1]Some cases did not provide the datum. [2]Mann Whitney U Test. [3]Kruskal-Wallis Test

* In bold, the values of significance of the differences between groups that were statistically significant (p<0.05)

Table 6 Factors associated to the presence of physical symptoms (according to score > 4 on PHQ-15 questionnaire)

	OR[1]	IC 95%		p
		Inferior	Superior	
Gender				
Man	1	-	-	-
Woman	1.5	1.2	1.9	0.002
Age				0.022
Under 30 years	1	-	-	-
Between 30 and 49 years	0.9	0.6	1.3	0.597
Between 50 and 69 years	0.7	0.4	1.0	0.055
70 years or more	0.5	0.2	0.9	0.014
Background of depression and/or anxiety				
Without backgrounds	1	-	-	-
With backgrounds	1.6	1.3	2.1	<0.001
Anxiety and/or depression according to DSM-IV				0.001
Depression	1	-	-	-
Anxiety	2.8	1.6	4.7	<0.001
Depression and anxiety	1.1	0.9	1.4	0.429
Concomitant psychiatric diagnosis				
Without concomitant diagnosis	1	-	-	-
With concomitant diagnosis	0.7	0.5	0.9	0.003
Concomitant conditions				
Without concomitant conditions	1	-	-	-
With concomitant conditions	1.6	1.2	2.1	0.004
Hepatic-digestive system conditions				
Without hepatic-digestive condition	1	-	-	-
With hepatic-digestive condition	3.5	1.4	8.9	0.007
Osteoarticular system condition				
Without osteoarticular system condition	1	-	-	-
With osteoarticular system condition	3.3	1.8	6.0	<0.001

[1] OR > 1 indicates association to an increase in the percentage of cases with the risk factor

DISCUSSION

Previous studies in our group show the increasingly higher prevalence of physical symptoms (somatization) in populations of patients with depression and/or anxiety (unpublished data) in our setting, which would at least partially explain the growing use of psychopharmaceuticals beyond the psychiatric consultations.[15] This fact makes the use of psychometric tools necessary for the analysis of these symptoms. One of these scales or questionnaires is the PHQ-15, a questionnaire that evaluates the severity of 15 of the most common physical symptoms. The purpose of this present work has been to validate the Spanish version of the PHQ-15 questionnaire for the evaluation of physical symptoms in patients with depression and/or anxiety disorders. The results obtained support the fact that the Spanish version of the PHQ-15 has acceptable feasibility, although 9.6% of his patients did not answer some of their 15 items. The results also confirm that the Spanish version of the PHQ-15 questionnaire has adequate reliability (Cronbach's Alpha coefficient of 0.78 for the global questionnaire) and adequate validity, including divergence/convergent (with correlations between moderate and high, these being between 0.3 in 0.5 with the MADRS scale), and

discriminant (significant differences were observed according to the different biosociodemographic and clinical characteristics) and predictive (some association was observed to certain clinical factors).

The PHQ-15 questionnaire has been used in many studies and translated to several languages.[14, 17, 18] We have been able to verify that the results found in our study are similar to previous studies on validation of this questionnaire in its original version, especially in regards to reliability and validity. More specifically, the reliability and validity of the original PHQ-15 questionnaire has been demonstrated in a study with 6000 patients, in which adequate internal consistency was found (0.8 Cronbach's Alpha coefficient), which is slightly higher than that observed in our study.[14]

In another previous study, that of Interian et al.,[7] the PHQ-15 questionnaire was validated in the North American population. Comparing this with the sociodemographic characteristics of our study, it can be observed that in the Interian et al. study, most of the patients were women (92%), with low education level, while in our study 65.5% were women and most of the patients had a middle-low level of studies. Another difference between both studies is that the Interian et al. study distinguished between Hispanic and non-Hispanic ethnic groups, while this distinction was not contemplated in our study. In any event, setting aside these differences between the sociodemographic characteristics of the samples of patients use, the compared reliability between both studies provides similar results. The Interian et al. study obtained a Cronbach's alpha coefficient of 0.79, very similar to that found in our study. In regards to the divergent/convergent validity, the results obtained in our study were also similar to those found in the Interian et al. study (with correlations of 0.3-0.7 in our study versus 0.44-0.68 in the mention study).

On the other hand, the factors associated to the presence of physical symptoms in our study population have been studied. As can be observed, we have found a clear association between the female gender and the presence of physical symptoms. This information confirms previous studies that show the greater prevalence of the association between physical symptoms and depression in women.[2] An association between backgrounds of depression and/or anxiety (OR=1.6) and the presence of anxiety (OR=2.8) and presence of physical symptoms that manifests the idea of the somatization of anxiety and/or depression states and that would at least partially explain the growing use of psychopharmaceuticals outside of the psychiatry consultations, also in primary care, was detected.[19] Furthermore, the logistic regression analyses conducted in our study confirmed, once again, the association observed between an elevated presence of "unexplained" physical symptoms and an elevated presence of some types of diseases. This would coincide with that described in previous works in relationship to some diseases that may be gastrointestinal[20] or osteoarticular,[21] conditions clearly associated to a certain level of anxiety and/or depression. A negative association in regards to age (>70 years) and severity of the physical symptoms collected in the PHQ-15 scale (with an OR of 0.5 (0.2-0.9, P=0.014) must also be mentioned. A plausible explanation of this fact could be a lower perception of the severity of the physical symptoms in elderly persons, compared with the younger population. This explanation could, in turn, be supported by the fact that patients >70 years take a greater number of drugs that may, to a certain degree mask the severity of the physical symptoms.

In conclusion, the results obtained with the Spanish version of the PHQ-15 questionnaire administered in Psychiatric Office Visits in Spain show that it is a measurement instrument with acceptable feasibility, reliability and valid to evaluate somatic symptoms associated to depression and/or anxiety, very prevalent in our current society.

Conflicts of interest

Dr. Salvador Ros Montalbán has been a consultant for Almirall, S.A. Mrs. Garcia-Garcia is an employee of Biometría Clínica, a CRO hired by Almirall, S.A. Dr. Comas is an employee of Almirall, S.A.

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Annex 1 — Patient Health Questionnaire PHQ-15

PATIENT HEALTH QUESTIONNAIRE PHQ-15

During the last 4 weeks, how much have you been bothered by any of the following problems?

	Not bothered	Bothered a little	Bothered a lot
a.- Stomach pain	1	2	3
b.- Back pain	1	2	3
c.- Pain in your arms, legs, or joints (knees, hips, etc.)	1	2	3
d.- Menstrual cramps or other problems with your periods (Women only)	1	2	3
e.- Headaches	1	2	3
f.- Chest pain	1	2	3
g.- Dizziness	1	2	3
h.- Fainting spells	1	2	3
i.- Feeling your heart pound or race	1	2	3
j.- Shortness of breath	1	2	3
k.- Pain or problems during sexual intercourse	1	2	3
l.- Constipation, loose bowels, or diarrhea	1	2	3
m.- Nausea, gas, or indigestion	1	2	3
n.- Feeling tired or having low energy	1	2	3
o.- Trouble sleeping	1	2	3