Validity and reliability of the WORRY-SR: a dimensional approach to the assessment of GAD spectrum

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Summary

Objectives
This study evaluates the validity and reliability of a new self-report instrument that assess GAD spectrum symptoms: the WORRY-SR.

Methods
Participants included 120 patients with mood and anxiety disorders recruited at the Department of Psychiatry of the University of Pisa and two comparison groups included 47 participants recruited at the Department of Occupational Medicine and 45 outpatients with gastrointestinal disorders. Participants completed the WORRY-SR, the Penn State Worry Questionnaire (PSWQ), the State Trait Anxiety Inventory (STAI), the Work and Social Adjustment Scale (WSAS), the Panic-Agoraphobia Spectrum (PAS-SR) and the WHO Quality of Life Assessment (WHOQOL-BREF).

Results
Internal consistency of the total WORRY-SR score (KR = 0.96) and for the domains (Childhood, Worry, Beliefs about Worry, Somatic and Emotional Symptoms, Cognitive Tendencies, and Behavioral and Interpersonal Tendencies) was excellent. Furthermore, the WORRY-SR showed good concurrent validity with the PSWQ (ρ = 0.71). Finally, the WORRY-SR discriminates participants with psychiatric disorders from controls and patients with severe functional impairment from those with mild/moderate functional impairment.

Conclusions
Our findings provide support for reliability and validity of the WORRY-SR questionnaire.

Key words

Worry • GAD • Dimensional approach • Self-report instrument • Functional impairment

Introduction

Generalized Anxiety Disorder (GAD) is defined as excessive, uncontrollable worry about a variety of topics that occurs more days than not for a period of at least six months. The worry must be associated with at least three of the following features: restlessness or feeling keyed up or on edge, being easily fatigued, difficulty concentrating or having one's mind go blank, irritability, muscle tension, and sleep disturbance with significant difficulty in controlling the anxiety and worry. The symptoms cause "clinically significant distress" or problems functioning in daily life and are not part of another mental disorder [1].
GAD was first introduced in the third edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-III; American Psychiatric Association) [2] but was most often used, in the DSM III, as a residual diagnosis for individuals who did not meet diagnostic criteria for a different anxiety disorder [3]. From the DSM III to the DSM III-R, the definition of GAD changed substantially: the time frame (from 1 month to 6 months); the number of symptoms (at least 6 symptoms required in 3 different categories), the presence of symptoms must not occur during the course of a mood disorder, and the diagnosis was allowed during childhood. Because of these changes, investigators, not surprisingly, found poor inter-rater agreement between GAD in the DSM-III and GAD in the DSM-III-R [4]. Some issues still surround the DSM-IV GAD criteria, particularly regarding the required duration, the concept of *excessive* worry (in the DSM-IV the worry no longer needed to be "unrealistic") and the number of associated symptoms. Recently, revisions for GAD have been proposed by the DSM-5 Anxiety Disorders Work Group [5] who evaluated in a recent paper [6] the utility of the proposed DSM-5 GAD diagnostic criteria indicating that these new criteria may increase the prevalence of GAD but the clinical utility, reliability and validity remain to be established.
First, the DSM-5 Work Group considered renaming Generalized Anxiety Disorder as Generalized Worry Disorder in order to emphasize the hallmark of GAD: the worry.

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Worry is the cognitive component, as distinct from the physiological symptoms, of anxiety. There appears to be consensus that worry is an avoidant coping strategy that is negatively enforced by reductions in patients' worry [6]. Furthermore, the authors proposed the deletion of symptoms that are non-specific to the GAD and the introduction of avoidance criteria consistent with the avoidance criteria for other anxiety disorders and with cognitive models of GAD [7 8]. Moreover, the authors proposed deleting DSM-IV criterion B because the literature underlined little effect of this criterion on identified cases. Finally, the DSM-5 Anxiety Disorders Work Group [5] questioned whether GAD exists as a disorder such as conceptualized in the DSM or if it is a dimension of illness. However, GAD remained as a separate diagnostic entity in DSM-5 [9], and it is still described with the same criteria of DSM-IV-TR [1].

The National Comorbidity Survey (NCS) estimated the lifetime prevalence of GAD, assessed using DSM-IV criteria, at about the 5.7% in the United States [10], and the ESEMED estimated the prevalence at 1.9% (95% CI 1.3-2.5) in Italy [11]. GAD appears to be twice as common in women as in men [6 12], and, differently from other anxiety disorders, is a disorder of adult onset [13 14]. Generalized Anxiety Disorder is not only highly prevalent, but is characterized by a chronic course, with significant impairment and risk of suicidality [15].

Patients with GAD report difficulties attributable to both physical and emotional symptoms, and frequently experience comorbid psychiatric and physical symptoms that often have no identifiable physiologic etiology [16 17]. The high level of comorbidity observed between GAD and other Axis I disorders (58-92%) lead some authors to wonder if GAD might be better conceptualized as a prodromal, a residual, or a severity marker of a comorbid disorder rather than an independent diagnostic category [4 18].

A recent review underlined that GAD was associated with a substantial human and economic burden [19]. Although in the NCS the course of GAD and its related impairment were unrelated with comorbidity with major depression [20], the high rates of comorbidity between GAD and major depression raised the question of whether GAD was a residual category or a prodromal of other anxiety or mood disorders. Moreover, the clinical presentation of GAD can differ markedly, depending on whether patients emphasize mental or somatic anxiety symptoms [21]. Several instruments already assess worry, such as the Penn State Worry Questionnaire (PSWQ) [22], or the Worry Domains Questionnaire (WDQ) [23]. Others instruments, such as the State-Trait-Anxiety-Inventory (STAI) [24] are more focused on a general dimension of anxiety. None of these instruments assesses somatic symptoms of anxiety. However, although excessive worry is the hallmark of GAD, the warning of potential danger and the anticipation of threat imply a persistent activation characterized by the presence of somatic symptoms that should be considered in any instrument assessing this psychopathological area. Consistently with our approach to other Axis I conditions (Spectrum Project, 1995-2016) and with the literature that argues that GAD signs and symptoms are lying along a dimensional *continuum* [25], we postulated the existence of a spectrum approach to GAD emphasizing soft signs and symptoms as well as a wide range of syndrome-level manifestations, that are surrounding the core features of the DSM-5 GAD diagnostic category. The proposed model point out the need for an enlargement of the psychopathological dimension of GAD, aiming at identifying those syndromes that are not fitting in the classic categorical description of DSM. The spectrum model was originally based upon the empirical observation that a wide range of psychopathologic signs and features not included in the DSM might run completely overlooked or considered not relevant from a clinical point of view. Conversely, a growing body of evidence indicates the clinical relevance of the sub-threshold and atypical presentations of a number of anxiety disorders, including GAD. This suggested the potential usefulness of a dimensional assessment of the psychopathological continuum encompassing all the manifestations of a disorder, including prodromal, atypical, residual manifestations or trait-like symptoms.

The aim of this study was to examine the reliability and validity of a new instrument to assess GAD spectrum symptoms, the WORRY-SR, in a sample of patients with mood and anxiety disorders and in two control groups without current psychiatric diagnoses.

Methods

Participants

A consecutive sample of outpatients (n = 120) presenting for treatment at the Department of Psychiatry in Pisa, Italy, from July 2008 to July 2009 were invited to participate in the study. Eligible patients included adults with mood and anxiety disorders. Exclusion criteria were severe medical illness, neurological diseases, or inability to participate because of the severity of psychiatric symptoms, the presence of current psychotic symptoms, and the presence of substance use disorders in the last 6 months, a diagnosis of hyperthyroidism, and poor knowledge of the Italian language. Control groups included 47 workers recruited during a routine visit at the Department of Occupational Medicine and 45 outpatients with gastrointestinal problems recruited at the Department of Gastroenterology in Pisa. The Ethics Committee of the Azienda Ospedaliero-Universitaria of Pisa approved all recruitment and assessment procedures. Participants provided written informed consent, after receiving a complete description of the study.

Instruments

The generalized anxiety disorder spectrum self-report: WORRY-SR

The WORRY-SR (see Appendix A) was developed by Italian and U.S. psychiatrists and clinical psychologists in the framework of the Spectrum Project. It includes 87 items exploring the "presence" or "absence" of lifetime symptoms conceptually organized into six domains: (1) Childhood, (2) Worry, (3) Beliefs about worry (4) Somatic and emotional symptoms, (5) Cognitive tendencies and (6) Behavioral and interpersonal tendencies. Item responses are coded dichotomously (yes/no) and total and domain scores are obtained by counting the number of positive answers.

The first domain, "Childhood", encompasses items referring to worry during childhood or adolescence, both about interpersonal relationships and about "potentially dangerous" situations.

The second domain, "Worry," is designed to capture the generality, excessiveness, and uncontrollability of the spectrum phenomenology of worry. This domain encompasses six subcategories: A) "General" focuses on worrying about the future; B) "Illness/health/injury" focuses on the state of a person's health or the health of those the person loves C) "Family/home/interpersonal" focuses on concerns regarding other persons; D) "Financial" focuses on worrying about spending money unwisely or concerns about not being able to unexpected financial issues; E) "Work/school" focuses on the feeling that one cannot live up to the expectations of the teachers/boss F) "Travel" focuses on apprehension about getting lost, having an accident or not bringing everything needed.

The third domain "Beliefs about worry" explores the "meta-worry" that is a variable consisting of the negative appraisal of worry. A useful way to think of meta-worry is as worrying about worrying[8]. This domain includes item such as "Have you often thought that other people are overly optimistic and that you are more realistic?" and "Have you often thought that worrying is a way to avoid risks?".

The fourth domain "Somatic and emotional symptoms" investigates somatic and emotional symptoms that are associated with hyper arousal.

The fifth domain "Cognitive tendencies" describes typical thoughts that an anxious person endorses, such as the thought the world is full of dangers or the thought that something terrible had happened if someone is late.

The last domain "Behavioral and interpersonal tendencies" describes all the behaviors related to experiential avoidance that plays a significant role in maintaining pathological behavioral and cognitive repertoires.

Mini International Neuropsychiatric Interview (M.I.N.I.) [26]

The M.I.N.I. is a standardized diagnostic interview used in clinical as well as research settings that allows one to make a diagnosis according to DSM-IV [27] and ICD-10 criteria [28]. It is organized in modules for Axis I diagnoses, suicide risk and antisocial personality disorder. The Italian version of the M.I.N.I. has been validated by Rossi et al. [29].

Work and Social Adjustment Scale (WSAS) [30]

The WSAS consists of 5 items rated, with reference to the week preceding the index visit, on an 8-point ordinal scale to assess social or occupational impairment in work, home management, social leisure activities, private leisure activities and the ability to form and maintain close relationships with others with reference to the week preceding the index visit. The total score is obtained as the sum of the 5 items and ranges from 0 to 40. Mundt et al. [30] suggested the use of cut-off scores to define three severity classes: no impairment (0-9), mild impairment (10-19), moderate to severe impairment (20-40).

State-Trait-Anxiety-Inventory (STAI) [24]

The STAI is a reliable and valid measure that has been used with both clinical and non-clinical populations. The measure comprises separate self-report scales for assessing state and trait anxiety. The state anxiety scale consists of 20 items that evaluate current feelings of tension, anxiety, and nervousness, while the 20-item trait scale assesses anxiety levels in general.

Panic-Agoraphobic Spectrum Self-Report (PAS-SR) [31]

The PAS-SR consists of 114 items coded as present or absent and assesses panic-agoraphobic spectrum symptoms occurring in the lifetime. This instrument consists of 114 items coded as present or absent items for one or more periods of at least 3 to 5 days in the lifetime. The factor analysis of the lifetime PAS-SR identified 10 factors: 'panic symptoms', 'agoraphobia', 'claustrophobia', 'separation anxiety', 'fear of losing control', 'drug sensitivity and phobia', 'medical reassurance', 'rescue object' (e.g. objects like water bottles, pills, umbrella, that are used to help the patient feel safer) 'loss sensitivity', and 'reassurance from family members' [32].

Penn State Worry Questionnaire (PSWQ) [22]

The PSWQ consists of 16 items rated on a 5-point ordinal scale and is a commonly used and psychometrically sound measure of the symptoms of pathological worry. Individuals diagnosed with generalized anxiety disorder (GAD), a condition characterized by excessive and uncontrollable worry, score significantly higher on the PSWQ than do those who meet only some of the GAD criteria.

WHOQoL-BREF [28]

The WHOQoL-BREF encompasses 26 items and allows a detailed assessment of 24 individual facets, related to quality of life. Facets are organized into four domains: physical health, psychological, social relationship and environment. Scores are expressed as percentages, where 0 denotes terrible and 100 excellent quality of life.

Statistical methods

Kuder-Richardson coefficient, a variant of the alpha coefficient [33], was used to test the internal consistency of domains and total score of the WORRY-SR. Test-retest reliability was examined using intra-class correlation coefficients [34 35]. Landis and Koch [36] criteria were used to characterize reliability levels as follows: 0-0.4 poor, 0.41-0.74 fair to good, 0.75-1 excellent. Convergent and divergent validity was analyzed using Spearman's correlation.

The scores of the WORRY-SR domains were compared among groups using ANOVA. The significance level was adjusted for multiple comparisons.

To determine if the WORRY-SR was able to discriminate the presence of comorbidity (having only one Axis I disorder *vs* having at least two Axis I disorders) and the presence of functional impairment (WSAS total score lower than 20 *vs* a WSAS total score of 20 or more), two receivers operating characteristic (ROC) analyses were carried out. In the ROC analysis, the sensitivity and specificity are plotted over the range of cut-off points [37]. The interpretation of the AUC values is traditionally the following: an AUC < 0.7 suggests "low" diagnostic accuracy, from 0.7 to 0.9 "moderate" diagnostic accuracy, and AUC ≥ 0.9 "high" diagnostic accuracy [38]. Analyses were carried out using SPSS version 20 for Windows (SPSS Inc. Chicago, IL, USA).

Results

Demographic and clinical characteristics of the study sample

Overall, 212 participants were recruited. Mean age was 40.8 ± 11.0 years, 68.4% were women and 31.6% men, 44.8% married, 13.7% separated or divorced, 40.1% never married, 45.3% had a high school diploma, 24.5% a university degree, 68.9% were employed. We compared the distribution of socio-demographic characteristics among psychiatric outpatients, outpatients with gastrointestinal disorders (GI), and participants recruited at the Department of Occupational Medicine (Table I). The study groups did not differ on gender, marital status and educational level. However, GI patients were younger than other two groups, and participants recruited at the Department of Occupational Medicine were more frequently employed than other two groups. Of the 212 par-

TABLE I.
Characteristics of the sample.

	Psychiatric outpatiens (N = 120)	Gastrointestinal outpatients (N = 45)	Occupational medicine patients (N = 47)	F or chi-square	p
Age (mean ± SD)	42.4 ± 11.4	36.4 ± 10.4*	41.1 ± 9.5	F = 4.95	0.008
Sex, F(%)	87 (72.5)	31 (68.9)	27 (57.4)	Chi2 = 3.55	0.170
Educational level, N(%)				Chi2 = 12.14	0.059
Primary school	1 (0.8)	0	1 (2.1)		
Secondary school	39 (32.5)	16 (35.6)	7 (14.9)		
High school (completed)	57 (47.5)	19 (42.2)	20 (42.6)		
University degree	23 (19.2)	10 (22.2)	19 (40.4)		
Employment status N (%)				Chi2 = 24.49	0.002
Student	14 (11.7)	8 (17.8)	2 (4.3)		
Unemployed	11 (9.2)	5 (11.1)	1 (2.1)		
Housewife	12 (10.0)	1 (2.2)	0		
Employed	72 (60.0)	31 (68.9)	43 (91.5)		
Retired	11 (9.2)	0	1 (2.1)		
Marital status N (%)				Chi2 = 4.28	0.639
Single	44 (36.7)	22 (48.9)	19 (40.4)		
Married	57 (47.5)	17 (37.8)	21 (44.7)		
Divorced	16 (13.3)	6 (13.3)	7 (14.9)		
Widowed	3 (2.5)	0	0		

TABLE II.
Current DSM IV diagnoses in the clinical sample.

Diagnosis	N (%)
Bipolar II	14 (6.6)
Major Depressive episode	28 (13.2)
Panic Disorder	27 (12.7)
Panic Disorder (Agoraphobia)	18 (8.5)
Agoraphobia without Panic	1 (0.5)
Social Phobia	5 (2.4)
Obsessive-Compulsive Disorder	5 (2.4)
Generalized Anxiety Disorder	29 (13.7)
Anorexia nervosa	1 (0.5)
Bulimia nervosa	1 (0.5)

ticipants, 75.5% (N = 160) had a lifetime DSM IV diagnosis (psychiatric outpatients: 100%; GI outpatients: 46.7% (21/45); participants recruited at the Department of Occupational Medicine: 40.4% (19/47)). 60.8% (N = 129) had at least 1 current diagnosis at index assessment (psychiatric outpatients: 85.8% (103/120); GI outpatients: 35.6% (16/45); participants recruited at the Department of Occupational Medicine: 21.3% (10/47). Table II reports current DSM diagnoses in the clinical sample.

Reliability of the WORRY-SR

Internal consistency of the total WORRY-SR score (KR = 0.96) and for the domains (Childhood, Worry, Beliefs about Worry, Somatic and Emotional Symptoms, Cognitive Tendencies, and Behavioral and Interpersonal Tendencies) was excellent (Table III).

To determine whether all theoretical domains belonged to a WORRY spectrum, we examined the properties of the scale that might suggest whether a given domain should be removed. Specifically, we calculated correlations of domain scores with the total WORRY-SR score and examined the effect of removal of each domain on the internal consistency of the scale (Kuder-Richardson's coefficient). All domains and sub-domains correlated with the WORRY-SR total score and the overall internal consistency decreased with the removal of each domain (Table III). Furthermore, correlations between domains were all positive and significant, with Spearman's ρ ranging between 0.443 and 0.779 ($p < 0.001$).

To evaluate test-retest reliability of the WORRY-SR, the questionnaire was re-administered after 7-14 days. The intra-class correlation of the total WORRY-SR score was ρ = 0.97 and that of the domains was ρ = 0.93 (Childhood), ρ = 0.96 (Worry), ρ = 0.93 (Beliefs about Worry), ρ = 0.93 (Somatic and Emotional Symptoms), ρ = 0.92 (Cognitive Tendencies), and ρ = 0.96 (Behavioral and Interpersonal Tendencies), suggesting excellent stability over a brief time span.

Convergent validity of the WORRY-SR

Spearman correlations with the WORRY-SR total score and PSWQ, STAI, PAS-SR total score and the "Panic symptoms" factor of the PAS-SR [32] were examined to assess the convergent validity of the WORRY-SR. Results indicate good convergent validity of the instrument: strong positive correlations were found between WORRY-SR total score and PSWQ (ρ = 0.71), STAI trait anxiety (ρ = 0.61), PAS-SR total score (ρ = 0.80)

Relationship between quality of life and functional impairment and WORRY-SR Scores

Spearman correlations with the WORRY-SR total score and WSAS, and WHOQOL-BREF were examined to assess the association between WORRY-SR and, quality

TABLE III.
Internal consistency (Kuder-Richardson coefficient) of domains of the WORRY-SR.

Worry-SR Domains	Domain total correlation	KR coefficient	Overall KR if domain deleted
Childhood	0.655	0.796	0.955
Worry	0.900	0.905	0.942
General	0.501	0.664	
Illness/Healthy/Injury	0.623	0.646	
Family/Home/Interpersonal	0.442	0.560	
Financial	0.692	0.768	
Work/School	0.554	0.768	
Travel	0.620	0.673	
Beliefs about worry	0.742	0.732	0.957
Somatic and emotional symptoms	0.525	0.828	0.955
Cognitive tendencies	0.782	0.836	0.953
Behavioral and interpersonal tendencies	0.676	0.842	0.954

TABLE IV.
Mean ± SD of the Worry-SR (domains and total score) in psychiatric patients and controls.

	Psychiatric outpatients (N = 120)	Gastrointestinal outpatients (N = 45)	Occupational medicine patients (N = 47)	F	P
Childhood	7.2 (3.4)	5.1 (3.5)*	3.8 (3.1)*	19.39	< 0.001
Worry	13.0 (7.0)	8.5 (5.7)*	7.3 (6.0)*	16.30	< 0.001
General	2.0 (1.4)	1.2 (1.1)*	1.1 (1.1)*	10.69	< 0.001
Illness/Healthy/Injury	2.2 (1.3)	1.4 (1.2)*	1.1 (1.1)*	13.87	< 0.001
Family/Home/Interpersonal	2.2 (1.2)	1.5 (1.1)*	1.3 (1.3)*	12.94	< 0.001
Financial	2.9 (2.3)	1.9 (1.8)*	1.6 (2.0)*	6.60	0.002
Work/School	2.4 (1.7)	1.7 (0.2)*	1.5 (0.2)*	8.92	< 0.001
Travel	1.3 (1.2)	0.8 (1.0)*	0.8 (1.0)*	6.54	0.002
Beliefs about worry	3.1 (2.0)	2.2 (2.0)	1.7 (1.8)*	9.09	< 0.001
Somatic and emotional symptoms	4.2 (1.6)	3.0 (2.0)*	2.4 (1.7)*	20.51	< 0.001
Cognitive tendencies	9.3 (3.6)	6.4 (4.8)*	5.2 (4.0)*	21.31	< 0.001
Behavioral and interpersonal tendencies	7.3 (3.6)	5.2 (3.6)*	3.9 (3.3)*	17.50	< 0.001
Total score	44.1 (17.5)	30.4 (19.1)*	24.3 (16.9)*	24.90	< 0.001

p < 0.016 *vs* Psychiatric outpatients group

of life and functional impairment. The WORRY-SR total score had a positive correlation with functional impairment ($\rho = 0.46$, $p < 0.001$), and a negative correlation with quality of life ($\rho = -0.54$, $p < 0.001$).

Discriminant validity of the WORRY SR

Participants recruited at the Department of Psychiatry showed significantly higher WORRY-SR total scores and domains scores as compared to control subjects.

Table IV reports mean total and domain scores on the WORRY-SR among the three study populations and suggest good discriminant validity. In order to further assess the ability of the WORRY-SR to discriminate patients with different levels of severity and impairment, we performed two ROC analyses. In the first model, we compared the WORRY-SR total score between patients with only one Axis I disorder (any diagnosis) and patients with at least two Axis I diagnoses. The AUC was 0.709 (95% CI 0.611-0.807), and at a cut-off score of 43 the sensitivity and the specificity were 0.77 and 0.59 respectively (Fig. 2). In Figure 1, we present the frequency distributions of the WORRY -SR total score in subjects with one Axis I diagnosis, two or more Axis I diagnoses and controls (panel A).

In the second model, we assessed whether the WORRY-SR discriminated between participants with severe functional impairment (WSAS total score of 20 or more) and participants with mild to moderate functional impairment (WSAS total score lower than 20). In Figure 1 (panel B), we report the distribution of WORRY-SR scores in these two groups of participants. The AUC was 0.680 (95% CI 0.58-0.78), and at a cut-off score of 43 the sensitivity and the specificity were 0.67 and 0.71 respectively (Fig. 2).

Discussion

The WORRY-SR is designed to assess lifetime anxiety symptoms according to a dimensional spectrum model of psychopathology [39 40]. This study provides evidence of the reliability and validity of the WORRY-SR. The instrument shows excellent internal consistency (0.96), with each domain correlating highly with the total score and the removal of any domain resulting in a lower overall KR coefficient. The convergent validity of the WORRY-SR *vs* the PSWQ, the STAI and the PAS-SR was good. The test-retest reliability of an instrument is a key psychometric property in clinical research.

The WORRY-SR showed, excellent stability of scores at 7-14 days, with an intra-class correlation of the total WORRY-SR score of $\rho = 0.88$ and correlations ranging between 0.92 and 0.96 for the individual domains. This finding was largely expected considering that the instrument assessed lifetime experiences and symptoms.

The comparison amongst psychiatric outpatients, gastrointestinal outpatients, and participants recruited at the Department of Occupational Medicine, showed that psychiatric outpatients scored significantly higher on both WORRY-SR total score and all WORRY-SR domains than each of the control groups. To further investigate the discriminant validity of the WORRY we conducted ROC analyses using two external validators as the "gold standard:" the presence of current Axis I comorbidity and the

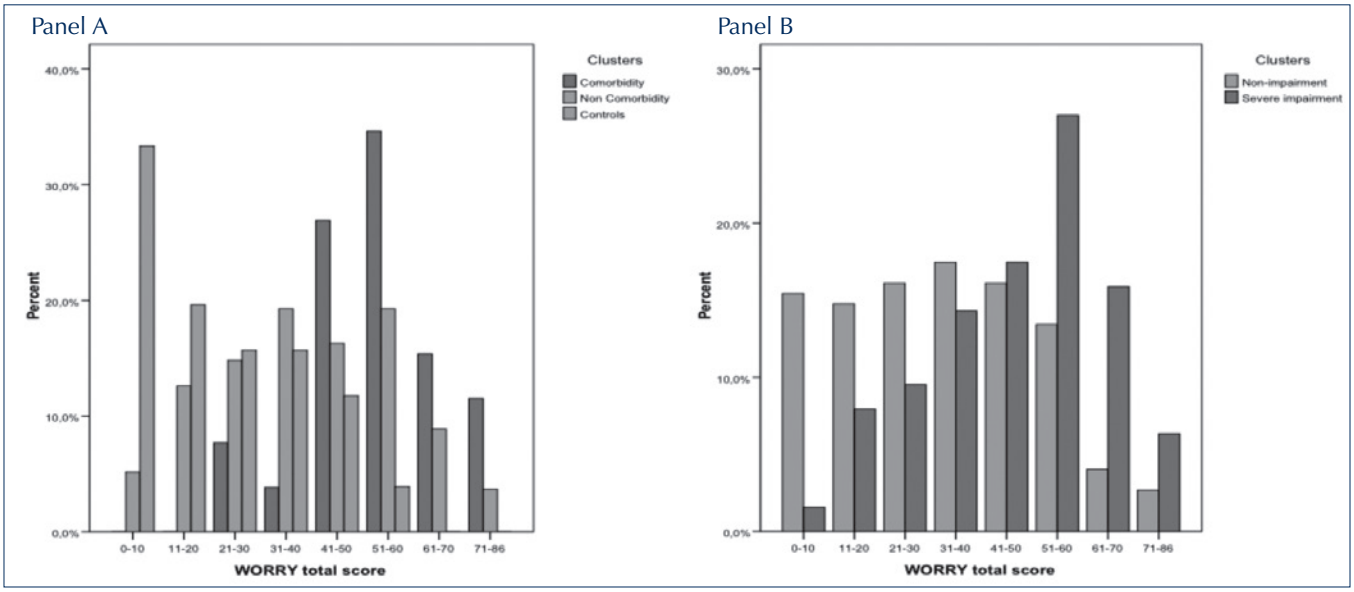

FIGURE 1.
Frequency distributions of the total Worry-SR score in subject with one Axis I diagnosis, tow or more Axis I diagnoses and controls (A) and in subjects with mild to moderate *vs* severe functional impairment (B).

presence of severe functional impairment assessed with the WSAS [30]. We found that a cut-off score of 43 or more on the total WORRY-SR score provides a useful threshold both for the presence of current comorbidity and for the presence of severe functional impairment. Taken together, these findings provide support for the coherence, validity and clinical utility of the WORRY-SR.

This study has several limitations. First, consistently with the NCS-R finding that the lifetime comorbidity of GAD with another Axis I diagnosis is 92.1% [10], we found a low prevalence of GAD as a single diagnosis. Therefore, we could not determine whether the WORRY-SR discriminates GAD patients from patients with other anxiety diagnoses. However, the literature underlines that the prevalence of

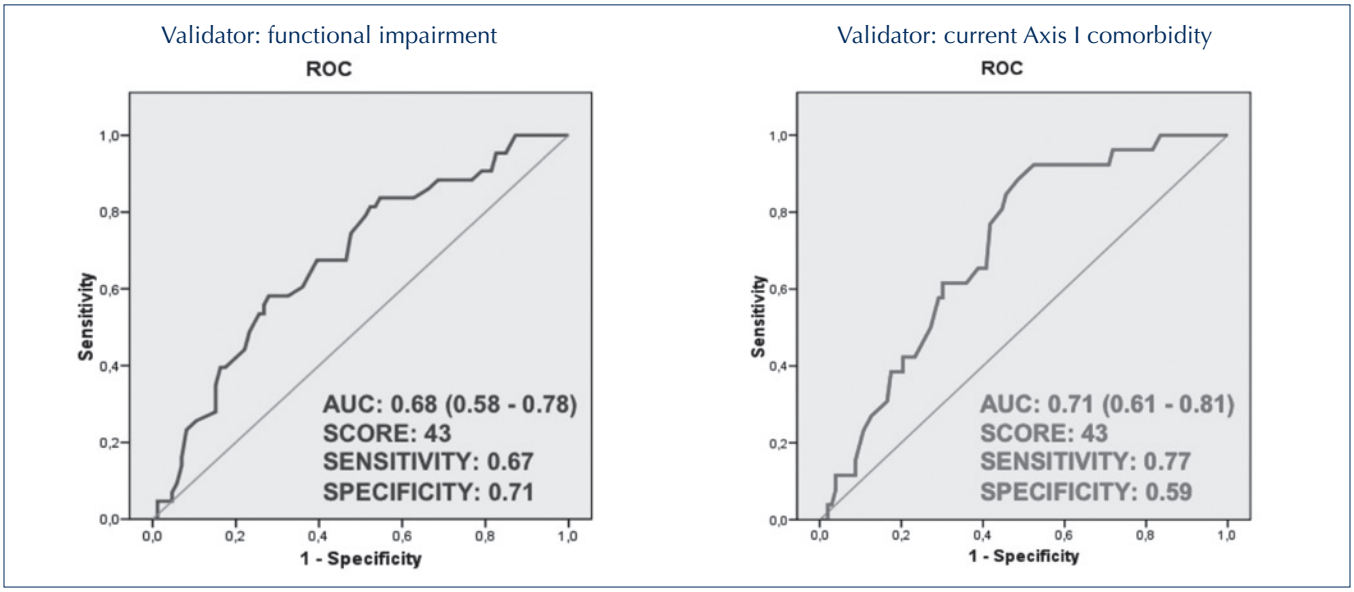

FIGURE 2.
Receiver operating characteristics.

GAD without any comorbid diagnosis was 0.4% in the NCS-R10, and 3.8% in primary care setting [41]. It is possible that the GAD spectrum explores a trans-nosographic dimension of both anxiety and mood disorders and not a specific feature of specific anxiety disorder [16]. It has been suggested that GAD could be considered the core anxiety disorder because worry, as its defining feature, reflects a basic process of anxiety [42 43]. For instance, Ruscio [44] reported that patients with GAD are not the only group that experiences high worry. A substantial proportion of non-GAD worriers experience the severity of worry that is associated with a GAD sample, but do not qualify for a GAD diagnosis because they do not endorse all DSM criteria [6].
Second, it is unclear whether the WORRY-SR comprises a single dimension or has a multi-dimensional structure. Given the number of items comprising the WORRY-SR, the present study did not have a sufficient sample size to conduct a factor analysis and address this important issue. However, it has been hypothesized that the cognitive and somatic features represented in the WORRY-SR could be different manifestations of worry spectrum. The introduction of somatic symptoms in a worry spectrum is an important issue. Although the PSWQ [22] is the measure most frequently used to assess pathological worry in both clinical and non-clinical populations, with sound psychometric properties [45] and useful in discriminating Social Anxiety from GAD [46], it focuses predominantly on cognitive features of GAD and does not include somatic features. Further research on this topic is needed to establish the prognostic and treatment implications of high WORRY-SR scores in different clinical samples.

Conflicts of interest

Mauro Mauri, Annalisa Oppo, Susanna Banti, Claudio Cargioli, Olivia Bacci and Jack D. Maser do not report potential conflicts of interest over the past 3 years.
Andrea Fagiolini is /has been a consultant and/or a speaker and/or has received research grants from: Allergan, Angelini, Astra Zeneca, Boehringer Ingelheim, Pfizer, Eli Lilly, Ferrer, Janssen, Lundbeck, Novartis, Otsuka, Roche
M.K. Shear reports the following potential conflict of interest over the past 3 years: a contract with Guilford Press to write a book on grief.

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Appendix

Worry-SR

Domain I: childhood

1. When you were a child, did you often feel insecure or uncomfortable in your relationship with your parents?
2. Did you worry about breaking rules set by your parents, or doing something that your parents told you not to, or that you would do something that would upset your parents?
3. Did you often worry that other people, like your friends and teachers, would disapprove of you or something you did?
4. As a child, did you worry a lot or did other people tell you that you did?
5. Did you have a lot of stomachaches or headaches?
6. Did you often have nightmares or bad dreams?
7. Did you ever become very anxious during a game because you thought you might win?
8. Did you always want someone else to go first because you wanted to be sure it was safe?
9. Did you often warn your friends not to do dangerous or risky things?
10. Did you worry more than other children you knew that you wouldn't learn or do well on an exam?
11. Did you worry a lot about family finances, or that there would be trouble in the family like illness or divorce?
12. Did you worry a lot about world disasters, crime, or war?
13. Did you worry a lot about getting sick?
14. Did you worry a lot about traveling, or when someone else had to travel, for example, on a train or on a plane?
15. Did you worry a lot in anticipation of a pleasant activity such as going on vacation, going to a party, or meeting friends?

Domain II: worry

A: general

Have you ever worried a lot…

16. that bad things could happen even if you knew they were unlikely?
17. that bad things could happen very far into the future?
18. about the well-being or happiness of others?
19. over minor matters?

B: illness/health/injury

Have you ever…

20. worried a lot about the state of your health or the health of those you love?
21. been called a hypochondriac?
22. worried that you or a loved one will get the wrong diagnosis, the wrong medicine or the wrong treatment?
23. worried that you or a loved one will die from a complication of a minor illness like the flu or a cold?
24. worried a lot that you or a loved one could easily get hurt or injured?

C: family/home/interpersonal

Have you ever worried a lot…

25. that you are not taking good enough care of your children, or that something bad will happen to your children?
    ___ *I don't have any children*
26. after you said or did something that offended someone?
27. that your friends or partner have stopped liking you?
28. have you ever tried to prevent your loved ones from doing things because you worried something bad might happen to them?

D: financial

Have you often worried…

29. that whatever you buy, you can't really afford it?
30. that whatever you buy, it will have something wrong with it or it won't work?
31. that something might break in your home or car and that it couldn't be easily fixed?
32. that you spent your money unwisely?
33. that you won't have enough money to pay your bills?
34. that you will not be able to provide for your family or support yourself?
35. that you won't have enough money in your old age?
36. do you save more money than most people with your income because you never know what the future will hold?

E: work/school

Have you often worried…

37. when you were in school, that you would fail even though you were doing fine in the class, or that you

would be fired from your job even though you had been told you were doing well?
38. that you would not live up to the expectations of your teachers or boss?
39. that you inadvertently broke the rules?
40. about minor things at school or work?
41. that you will not understand instructions or you will make a mistake when given a task to do?

F: travel

When you or your relatives travel, have you often worried…

42. that you will get lost or have an accident?
43. that you didn't bring everything you will need?
44. that things will go wrong, such as your reservations will be mixed up or lost, that the place you will stay will be terrible, that you will misplace your itinerary or maps, that the weather will be bad, that you will miss your connections, or that your luggage will get lost?

Domain III: beliefs about worry

Have you often thought that…

45. worrying helps motivate you to get things done?
46. worrying is a way to avoid risks?
47. other people are overly optimistic and that you are more realistic?
48. worrying about something is the only way you can gain control over it?
49. worrying about something is a way to prepare yourself for the worst?

Have you often…

50. worried that you have done something wrong in the past and you will eventually be punished?
51. criticized yourself for worrying?

Domain IV: somatic and emotional symptoms

Have you ever had periods when you felt…

52. nervous, tense, restless, keyed up or on edge?
53. muscle aches, twitching or shaky?
54. your stomach churning or that you had an upset stomach or diarrhea?
55. physical symptoms like you were out of breath, your heart was beating too fast, your hands were cold or sweaty, your mouth was dry?
56. tired or exhausted?
57. irritable?

Have you ever had periods when you felt that you…

58. talked too much, too fast, or too loud when you were worried?
59. had difficulty concentrating or found that your mind went blank?
60. couldn't fall asleep because your mind was racing?
61. had trouble staying asleep?
62. couldn't control your worrying?
63. wanted to stop yourself from worrying?
64. Have you often felt a sense of impending doom or nameless dread?

Have you ever…

65. used food to distract yourself from worrying?
66. used drugs or alcohol to distract yourself from worrying?

Domain V: cognitive tendencies

Have you ever had a period when you…

67. thought the worst when the slightest thing went wrong?
68. thought that something terrible had happened if someone was late?
69. felt that you were unable to cope whenever anything went wrong?
70. felt overwhelmed by everyday hassles?
71. thought that you couldn't be too careful?
72. worried that you would forget something important?
73. thought the world was full of dangers?

Have you often…

74. thought when you heard an ambulance or saw an accident, that it might be someone in your family who was ill or injured?
75. had a sudden thought about something bad that might happen?

Domain VI: behavioral and interpersonal tendencies

Are you the kind of person who….

76. avoids taking risks, even when the payoff might be high?
77. is constantly on guard and cannot relax?

78. is very uncomfortable when things are uncertain?
79. is very uncomfortable when you have to wait, for example, for a train, in line at a shop, at the doctor's office, for the results of a test, for someone to call or come home or wake up?
80. can't tolerate being late?
81. needs to check on things that you are worried about, like why someone didn't call or didn't arrive on time?

Do you think…

82. it is your nature to worry and there is no way to worry less?
83. you worry too much and your worries are not that realistic?
84. about worrying or talk a lot about your worries to your friends?
85. you are a pessimist?
86. Do other people tell you that you worry too much?