A Clinically Useful Self-Report Measure of the *DSM-5* Anxious Distress Specifier for Major Depressive Disorder

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ABSTRACT

Objective: To acknowledge the clinical significance of anxiety in depressed patients, *DSM-5* included criteria for an anxious distress specifier for major depressive disorder. In the present report from the Rhode Island Methods to Improve Diagnostic Assessment and Services (MIDAS) project, we modified our previously published depression scale to include a subscale assessing the *DSM-5* anxious distress specifier.

Method: From December 1995 to August 2013, 773 psychiatric outpatients with major depressive disorder completed the Clinically Useful Depression Outcome Scale (CUDOS) supplemented with questions for the *DSM-5* anxious distress specifier (CUDOS-A). To examine discriminant and convergent validity, the patients were rated on clinician severity indices of depression, anxiety, and irritability. Discriminant and convergent validity was further examined in a subset of patients who completed other self-report symptom severity scales. Test-retest reliability was examined in a subset who completed the CUDOS-A twice. We compared patients who did and did not meet the *DSM-5* anxious distress specifier on indices of psychosocial functioning and quality of life.

Results: The CUDOS-A subscale had high internal consistency and test-retest reliability; was more highly correlated with other self-report measures of anxiety than with measures of depression, substance use problems, eating disorders, and anger; and was more highly correlated with clinician severity ratings of anxiety than depression and irritability. CUDOS-A scores were significantly higher in depressed outpatients with a current anxiety disorder than in depressed patients without a comorbid anxiety disorder ($P < .001$). Finally, patients who met the *DSM-5* anxious distress specifier reported poorer psychosocial functioning and quality of life than patients who did not meet the anxious distress specifier.

Conclusions: In the present study of a large sample of psychiatric outpatients, the CUDOS-A was a reliable and valid measure of the *DSM-5* anxious distress specifier for major depressive disorder.

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During the past 20 years, the clinical significance of coexisting anxiety disorders and anxiety symptoms in depressed patients has been increasingly recognized. Prevalence is high, with the majority of depressed patients having symptoms of anxiety or a comorbid anxiety disorder.[1–3] Anxiety in depressed patients predicts greater morbidity. Co-occurring anxiety has been associated with increased suicidality,[4–6] greater impairment in functioning,[7] worse health-related quality of life,[8] poorer longitudinal course,[7–16] greater number of depressive episodes,[5,17] and poorer response to treatment in controlled efficacy studies[18–20] and uncontrolled effectiveness studies.[17,21] The presence of anxious features has also been associated with differential treatment response in some studies.[22–26]

To acknowledge the clinical significance of anxious features in depressed patients, *DSM-5* included criteria for an anxious distress specifier for major depressive disorder.[27] With the increased attention likely to be given to anxious depression because of the addition of this specifier in *DSM-5*, it is important that rating scales be developed that measure symptoms of both depression and anxiety. This is particularly timely in the context of recent recommendations to measure outcome during routine clinical practice.[28] Measurement-based care has been emphasized in official treatment guidelines for depression,[28] as well as *DSM-5*. Self-report questionnaires are a cost-effective option to implement measurement-based care because they are inexpensive in terms of professional time needed for administration, and they correlate highly with clinician ratings.[29] However, self-report scales also need to attend to the issue of length and completion time if repeated measurement is to be feasibly incorporated into clinical practice.

In the present report from the Rhode Island Methods to Improve Diagnostic Assessment and Services (MIDAS) project, we describe a modification of a self-administered depression scale (the Clinically Useful Depression Outcome Scale [CUDOS]) developed in our clinical research program to include a subscale assessing the *DSM-5* anxious distress specifier for major depressive disorder (CUDOS-A). We examined the subscale's psychometric properties, its convergent and discriminant validity, its association with clinician ratings of anxiety severity and anxiety disorder diagnoses, and its association with psychosocial functioning and quality of life. We hypothesized that the CUDOS-A would demonstrate acceptable reliability, that it would be more highly correlated with other indices of anxiety than nonanxious constructs, and that depressed patients who met the *DSM-5* anxious distress specifier would report greater psychosocial impairment and poorer quality of life than depressed patients who did not meet the anxious distress specifier.

METHOD

Patients presenting for an intake evaluation at the Rhode Island Hospital Department of Psychiatry outpatient practice were asked to complete self-report questionnaires as part of their initial paperwork.

Clinical Points

- Anxiety is frequent in depressed patients and is associated with greater psychosocial morbidity and poorer response to treatment.
- To acknowledge the clinical significance of anxious features in depressed patients, *DSM-5* included criteria for an anxious distress specifier for major depressive disorder.
- In the present study of a large sample of psychiatric outpatients, the Clinically Useful Depression Outcome Scale supplemented with questions for the *DSM-5* anxious distress specifier (CUDOS-A) was a reliable and valid measure of the *DSM-5* anxious distress specifier for major depressive disorder.

Because we were planning to test the validity of the scales we were developing by examining their relationship with psychiatric diagnoses, the diagnosticians were kept blind to the subjects' responses on the measure. The Rhode Island Hospital institutional review committee approved the research protocol, and all patients provided informed, written consent. The study was conducted from December 1995 to August 2013.

The sample examined in the present report is derived from the 3,800 psychiatric outpatients evaluated with semistructured diagnostic interviews. Throughout the MIDAS project, the battery of questionnaires changed, and not all patients completed all questionnaires. The present report focuses on the 773 patients diagnosed with major depressive disorder who completed the CUDOS-A. The majority of the patients were female (64.8%, n = 501), were white (88.2%, n = 682), and had achieved high school graduation or a higher level of education (93.4%, n = 722). The mean age of the sample was 41.1 years (SD = 12.6).

The CUDOS is a brief measure of depression severity that assesses the *DSM-IV* (and *DSM-5*) symptoms of major depressive disorder.[30] Compound *DSM-IV* depression symptom criteria referring to more than 1 construct (eg, increased or decreased appetite; insomnia or hypersomnia) were subdivided into their respective components, and a CUDOS item was written for each component. Distinguishing typical and reverse vegetative features of depression is particularly important in a scale to be used to assess both depression and anxiety because atypical features of depression are associated with anxiety.[31] Each of the CUDOS items is rated on a 5-point ordinal scale to indicate the frequency of the symptom during the past week (0 = not at all true, 1 = rarely true, 2 = sometimes true, 3 = often true, 4 = almost always true). An ordinal rating was preferred in order to keep the scale brief and therefore less burdensome to complete in routine clinical practice.[32] The scale's internal consistency reliability coefficient (Cronbach $\alpha = 0.90$) and test-retest reliability ($r = 0.92$) were high. The CUDOS was more highly correlated with other measures of depression than with measures of the other symptom domains, thereby supporting the scale's convergent and discriminant validity.

The content of the CUDOS-A subscale was based on the *DSM-5* criteria for the anxious distress specifier. The 5 symptoms of the anxious distress specifier are as follows: feeling keyed up or tense, feeling restless, having difficulty concentrating because of worry, fearing that something awful might happen, and feeling that one might lose control. The items for the anxious distress specifier were drawn from a larger pool of 113 items assessing symptoms of anxiety. The pool of items was reviewed by clinicians experienced in treating mood and anxiety disorders, and consensus was reached regarding the items assessing the 5 criteria of the *DSM-5* specifier. The respondent rated the 5 CUDOS-A items on the same 5-point ordinal scale used to rate the symptoms of depression.

All patients were interviewed by a trained diagnostic rater who administered the Structured Clinical Interview for *DSM-IV* (SCID)[33] supplemented with questions from the Schedule for Affective Disorders and Schizophrenia (SADS)[34] assessing the severity of symptoms during the week prior to the evaluation. Of particular interest to the current report is that all patients were evaluated on the SADS items assessing psychic anxiety, depressed mood, and irritability. Details regarding interviewer training and diagnostic reliability are available in other publications from the MIDAS project, which have documented high reliability in diagnosing anxiety disorders and major depressive disorder.[35–37]

To examine the convergent and discriminant validity of the CUDOS-A, the patients completed a booklet of questionnaires at home that included measures of symptoms related to bulimia,[38] mania,[39] depression,[40] social phobia,[41,42] agoraphobic fears and cognitions,[42,43] posttraumatic stress disorder,[44] obsessive-compulsive behavior,[45] cognitions common in generalized anxiety,[46] anxiety symptoms and cognitions common in panic disorder,[47] alcohol use,[48] drug use,[49] hypochondriasis,[50] and somatization.[51,52] Most of these scales have been widely used, and their reliability and validity well established.

The Diagnostic Inventory for Depression (DID)[53] is a self-report scale designed to assess the *DSM-IV* symptom inclusion criteria for a major depressive episode, assess psychosocial impairment due to depression, and evaluate subjective quality of life. A modification of the psychosocial functioning and quality of life subscales was used in the present study such that respondents rated how much difficulty "emotional problems" caused in psychosocial functioning and quality of life. (On the DID, the respondent indicates how much difficulty symptoms of depression cause in functioning or life satisfaction.) The 6-item psychosocial functioning subscale assesses the amount of difficulty in usual daily responsibilities, relationships with significant others such as spouse, relationships with close family members, relationships with friends, participation in leisure activities, and overall function. Items are rated on a 5-point ordinal scale (0 = no difficulty to 4 = extreme difficulty). The quality of life subscale assesses satisfaction with the same areas covered by the psychosocial functioning scale as well

Table 1. Item-Total Correlations and Test-Retest Reliability of Clinically Useful Depression Outcome Scale—Anxious Distress Specifier Subscale (CUDOS-A) Items

CUDOS-A Item	Item-Total Correlations[a,b] (n = 773)	Test-Retest Reliability[b] (n = 58)
I felt keyed up or on edge because I was worried about things	0.69	0.78
I felt very fidgety, making it difficult to sit still	0.41	0.78
I had difficulty concentrating because my mind was on my worries	0.61	0.64
I worried a lot that something bad might happen	0.60	0.84
When I was extremely anxious, I was afraid I would lose control	0.54	0.84

[a]The total score in the item-total correlations did not include the item correlated with the total.
[b]All correlations are significant at $P < .001$.

as global satisfaction with mental health and physical health. Items are rated on a 5-point Likert scale (0 = very satisfied to 4 = very dissatisfied). The quality of life and psychosocial impairment subscales achieved high levels of internal consistency and test-retest reliability.[53]

The test-retest reliability of the CUDOS-A was examined in 58 patients who completed the measure at the time of their first appointment and were given the scale at the conclusion of the intake evaluation and asked to mail it back in a pre-addressed, postage-paid envelope. They were told that the purpose of the second administration was to test the performance of the scale, not to question the truthfulness or accuracy of their responses. Patients completed the second administration a mean of 3.3 days (SD = 9.2) after the initial testing.

Data Analyses

We undertook a series of 5 analyses. First, we examined 2 types of reliability of the CUDOS-A: test-retest reliability and internal consistency. We examined the reliability of the total scale score as well as individual items. Second, we examined convergent and discriminant validity[54] by comparing the correlation between the CUDOS-A and self-report measures of anxious symptoms with the correlation between the CUDOS-A and measures of depression, substance use, eating disorders, and somatization. We also compared the correlation between the CUDOS-A and the SADS ratings of psychic anxiety to the correlations between the CUDOS-A and the SADS ratings of depressed and irritable mood by calculating the difference between the Fisher *z* transformations of the correlation coefficients and dividing the difference by the standard error. Third, we used *t* tests to determine whether CUDOS-A scores were significantly higher in patients with anxiety disorders than in those without an anxiety disorder. Fourth, we computed correlations between scores on the CUDOS-A with global ratings of psychosocial functioning and quality of life. Fifth, we compared psychosocial functioning and quality of life scores in patients who did and did not meet the *DSM-5* anxious distress specifier on the CUDOS-A.

Table 2. Discriminant and Convergent Validity of the Clinically Useful Depression Outcome Scale—Anxious Distress Specifier Subscale (CUDOS-A)

Measure	Correlation With CUDOS-A, *r*[a] (n = 204)
Anxiety symptoms	
Beck Anxiety Inventory	0.69
Penn State Worry Scale	0.55
Social Phobia and Agoraphobia Inventory-Agoraphobia	0.59
Anxiety Sensitivity Index	0.64
Posttraumatic Stress Disorder Scale	0.38
Maudsley Obsession-Compulsive Inventory	0.39
Fear Questionnaire Social Phobia Subscale	0.44
Nonanxious symptoms	
Eating Disorder Inventory Bulimia Subscale	0.21
Eating Disorder Inventory Anorexia Subscale	0.13
Self Report Mania Inventory	0.44
Symptom Rating Test Paranoia Subscale	0.44
Symptom Rating Test Psychosis Subscale	0.29
Beck Depression Inventory	0.55
Michigan Alcohol Screening Test	0.08
Drug Abuse Screening Test	0.11

[a]Because of missing data, the sample sizes ranged from 195 to 204 except for the Maudsley Obsession-Compulsive Inventory (n = 109). All correlations are significant at $P < .001$ except Self Eating Disorder Inventory Bulimia Subscale ($P < .05$), Eating Disorder Inventory Anorexia Subscale ($P = .06$), Michigan Alcohol Screening Test ($P = .27$), and Drug Abuse Screening Test ($P = .14$).

RESULTS

Internal Consistency and Test-Retest Reliability of the CUDOS-A

The 5-item CUDOS-A subscale demonstrated very good internal consistency (Cronbach $\alpha = 0.79$). The data in Table 1 show the correlation between each of the 5 items and the total scale score (minus the contribution of that item). All item-scale correlations were significant (mean $r = 0.57$).

The test-retest reliability of the CUDOS-A was examined in 58 subjects. The test-retest reliability of the total scale was high ($r = 0.89$), and the test-retest reliability of each item was significant (mean $r = 0.78$) (Table 1).

Discriminant and Convergent Validity of the CUDOS-A

Two hundred four patients completed a package of questionnaires at home a mean of 1.2 days (SD = 16.9) after the intake evaluation. The data in Table 2 show that the CUDOS-A was more highly correlated with other measures of anxiety symptoms (mean $r = 0.53$) than with measures of the other symptom domains (mean $r = 0.28$). The CUDOS-A was not significantly correlated with measures of substance use or anorexia.

To further explore the relationship between the CUDOS-A and ratings of affective dimensions, we examined the association between the scale and clinicians' ratings on the SADS items for depressed mood, psychic anxiety, and irritability. The ratings were made blind to scores on the CUDOS-A. The correlation with the anxiety rating was significantly higher than the correlation with the depressed mood rating (0.47 vs 0.16, $z = -6.56$, $P < .01$) and significantly

Table 3. Clinically Useful Depression Outcome Scale—Anxious Distress Specifier Subscale (CUDOS-A) Scores in Psychiatric Outpatients With and Without a Current *DSM-IV* Anxiety Disorder

		CUDOS-A Total			*P*
Current Anxiety Disorder	n	Mean	SD	*t*[a]	Value
Panic disorder	177	13.6	4.5	10.5	<.001
Generalized anxiety disorder	202	12.4	4.1	8.5	<.001
Social phobia	251	11.6	4.7	6.4	<.001
Specific phobia	107	13.4	4.6	8.0	<.001
Obsessive-compulsive disorder	51	13.6	4.5	6.4	<.001
Posttraumatic stress disorder	120	12.9	4.6	7.5	<.001
No anxiety disorder	260	8.9	4.9		

[a]CUDOS-A scores were compared between each anxiety disorder and the no anxiety disorder group.

Table 4. Psychosocial Functioning in Depressed Outpatients Who Did and Did Not Meet the *DSM-5* Anxious Distress Specifier on the Clinically Useful Depression Outcome Scale—Anxious Distress Specifier Subscale

	Anxious Specifier Present (n = 370)		Anxious Specifier Absent (n = 171)			*P*
Domain	Mean	SD	Mean	SD	*t*	Value
Work performance	2.6	1.4	1.8	1.4	−6.0	<.001
Marital relationship	2.6	1.3	1.8	1.4	−6.8	<.001
Family relationships	2.0	1.4	1.4	1.3	−5.1	<.001
Friendships	1.8	1.4	1.1	1.3	−5.2	<.001
Leisure	2.8	1.3	2.1	1.4	−5.4	<.001
Global rating of impairment	3.2	0.8	2.4	1.0	−8.6	<.001

higher than the correlation with the irritable mood item (0.47 vs 0.25, $z = -5.00$, $P < .01$).

Association With Psychiatric Diagnosis

Across all patients, the mean score on the CUDOS-A subscale was 11.0 (SD = 5.0). Patients with any *DSM-IV* anxiety disorder (n = 513) scored significantly higher than patients with no current anxiety disorder (n = 260) (12.1 ± 4.7 vs 8.9 ± 4.9, $t_{771} = 8.7$, $P < .001$). We examined CUDOS-A scores in patients with each of the *DSM-IV* anxiety disorders. The comparison group in each of these analyses was the 260 patients without a current anxiety disorder. The data in Table 3 show that for each of the 6 anxiety disorders, patients with the disorder scored significantly higher than patients with no current anxiety disorder.

Because anxiety disorders frequently co-occur, some disorders may have been significantly associated with CUDOS-A scores by virtue of their association with other anxiety disorders. The majority of patients with each anxiety disorder were diagnosed with at least 1 other anxiety disorder (panic disorder, 72%; generalized anxiety disorder, 68%; social phobia, 68%; specific phobia, 86%; posttraumatic stress disorder, 79%; obsessive-compulsive disorder, 73%). We conducted a second series of analyses and included in the index group patients with the index anxiety disorder and no other anxiety disorder. For example, the panic disorder group included the 50 patients with panic disorder and no other anxiety disorder. In each of these analyses, the comparison group remained the 260 patients without a current anxiety disorder. For 4 of the 6 anxiety disorders, patients with the "pure" noncomorbid anxiety disorders scored significantly higher on the CUDOS-A (panic disorder [n = 50]: 13.1 ± 4.8 vs 8.9 ± 4.9, $t_{308} = 5.5$, $P < .001$; generalized anxiety disorder [n = 64]: 11.1 ± 4.2 vs 8.9 ± 4.9, $t_{322} = 3.3$, $P < .001$; social phobia [n = 86]: 9.4 ± 4.8 vs 8.9 ± 4.9, $t_{344} = 0.8$, NS; specific phobia [n = 15]: 14.0 ± 5.0 vs 8.9 ± 4.9, $t_{273} = 3.9$, $P < .001$; obsessive-compulsive disorder [n = 14]: 10.9 ± 5.0 vs 8.9 ± 4.9, $t_{272} = 1.8$, NS; posttraumatic stress disorder [n = 27]: 11.8 ± 5.1 vs 8.9 ± 4.9, $t_{285} = 2.9$, $P < .05$).

Table 5. Quality of Life in Depressed Outpatients Who Did and Did Not Meet the *DSM-5* Anxious Distress Specifier on the Clinically Useful Depression Outcome Scale—Anxious Distress Specifier Subscale

	Anxious Specifier Present (n = 362)		Anxious Specifier Absent (n = 170)			*P*
Domain	Mean	SD	Mean	SD	*t*	Value
Work performance	2.4	1.4	2.3	1.2	−1.0	NS
Marital relationship	2.2	1.4	1.3	1.3	−4.0	<.05
Family relationships	1.6	1.3	0.6	1.0	−1.9	NS
Friendships	1.8	1.2	1.5	1.1	−2.1	<.05
Leisure	2.7	1.2	2.5	1.1	−1.5	NS
Mental health	3.3	0.9	2.7	1.1	−5.3	<.001
Physical health	2.4	1.2	2.0	1.2	−3.1	<.05
Global rating of life satisfaction	3.2	0.8	2.7	0.9	−6.2	<.001
Global rating of quality of life	2.8	0.7	2.4	0.7	−5.8	<.001

Association With Quality of Life and Psychosocial Functioning

Higher scores on the CUDOS-A subscale were associated with global ratings of functional impairment ($r = 0.41$, $P < .001$), reduced life satisfaction ($r = 0.31$, $P < .001$), poorer quality of life ($r = 0.33$, $P < .001$), poorer mental health ($r = 0.27$, $P < .001$), and poorer physical health ($r = 0.18$, $P < .001$).

The *DSM-5* anxious distress specifier requires the presence of 2 or more of the 5 criteria, and we used the CUDOS-A to subtype the patients into those who did and did not meet the *DSM-5* definition. More than two-thirds of the patients met the *DSM-5* anxious distress specifier according to the CUDOS-A. The data in Tables 4 and 5 show that the patients who met the *DSM-5* anxious distress specifier reported significantly more impaired functioning and poorer quality of life than the patients who did not meet the *DSM-5* anxious distress specifier.

DISCUSSION

In the present study, the CUDOS-A was found to be a reliable and valid measure of anxiety symptoms in depressed patients. The scale was more highly correlated with other self-report measures of anxiety than with measures of depression, substance use problems, eating disorders, and anger. The convergent and discriminant validity of the CUDOS-A was further supported by the finding that the measure was more highly correlated with clinician severity ratings of anxiety than depression and irritability. In addition, CUDOS-A scores were significantly higher in depressed outpatients with anxiety disorders than depressed outpatients without an

anxiety disorder. Consistent with other research on the high prevalence of anxiety in depressed patients, the majority of depressed patients met the *DSM-5* anxious distress specifier on the CUDOS-A, and compared to patients who did not meet the *DSM-5* specifier, the patients who met the anxious distress specifier reported more functional impairment and poorer quality of life.

It has recently been recommended that standardized scales be incorporated into clinical practice to measure outcome when treating depression.[55,56] Few psychiatrists, however, routinely use scales to measure outcome.[57,58] To achieve this goal, the measurement tools used in clinical practice should be meaningful to the patient; otherwise, there is a risk of patient opposition to measurement. Anxiety is common in depressed patients; therefore, the addition of a small number of items assessing anxiety symptoms to a measure of depression is unlikely to meet with resistance and seems advisable.

During the past 2 decades, a large literature has established the clinical significance of anxiety in depressed patients. Anxiety symptoms are present in the majority of depressed patients and predict a poorer response to treatment, a more chronic longitudinal course, increased risk of suicidal behavior, and greater psychosocial impairment.[59] A number of studies have focused on the impact of anxiety in the treatment of depressed patients[17,22,26,60–63]; however, there is relatively little evidence that anxiety moderates treatment response to different antidepressants.[64] Nonetheless, clinicians indicated that anxiety was the symptom that most commonly influenced their choice of antidepressant in depressed patients.[65]

The CUDOS-A is the fourth in a series of "Clinically Useful" scales that we have developed for use in clinical practice. Previously, we described our development and validation of such a measure for depression (CUDOS), anxiety (Clinically Useful Anxiety Outcome Scale),[66] and social anxiety (Clinically Useful Social Anxiety Disorder Outcome Scale).[67] Each of the scales in the Clinically Useful series is intended to be brief, easily scored, and available to clinicians for personal use without cost. Each scale has the same rating instructions, thereby facilitating comparisons of symptom severity across varied symptom domains.

While each of the scales we have developed was intended to be brief and therefore more readily incorporated into routine clinical practice, we are not aware of any studies demonstrating that briefer scales are more likely to be used by clinicians than longer scales. However, a study of depressed patients' acceptance of measurement-based care in clinical practice found that patients preferred to complete a briefer measure to monitor their progress.[32]

The Hospital Anxiety and Depression Scale (HADS) is another brief self-report instrument assessing both depression and anxiety symptoms.[68] In contrast to the CUDOS-A, the HADS was not designed to assess the *DSM-5* criteria for major depressive disorder or the anxious distress specifier. Most of the criteria for *DSM-5* major depressive disorder, such as sleep disturbance, appetite disturbance, fatigue, guilt, worthlessness, and suicidal thoughts, are not assessed on the HADS. Future research should examine the relationship between the HADS and the CUDOS-A and their respective relationship to a clinician-administered assessment of the *DSM-5* anxious distress specifier.

A limitation of the study was that our diagnostic evaluation did not include the questions assessing the *DSM-5* anxious distress subtype; thus, we were unable to establish the concordance between the CUDOS-A with a clinician-administered diagnostic interview. However, the prevalence of anxious depression according to the CUDOS-A and the differences between patients who did and did not meet the anxiety distress specifier in psychosocial functioning and quality of life are consistent with prior research and support the measure's validity.

We found that the prevalence of the *DSM-5* anxious distress specifier was high, although nearly identical to the frequency of anxiety disorders in the MIDAS project when diagnoses were based on a semistructured interview and included not otherwise specified anxiety disorder and anxiety disorders that were in partial remission.[3] However, it should be noted that the CUDOS-A is a cross-sectional measure of symptoms that are present during the past week. The *DSM-5* definition of the anxious distress specifier requires that the anxiety symptoms be present the majority of the days of the major depressive episode. Consequently, it is likely that a cross-sectional measure of the symptoms of the *DSM-5* anxious distress specifier will overestimate the prevalence of patients who meet the criteria for the specifier.

The study was conducted in a single clinical practice in which the majority of the patients were white, were female, and had health insurance. Replication in samples with different demographic characteristics is warranted. However, the generalizability of the findings is enhanced by the lack of inclusion and exclusion criteria to select patients.

Almost all patients were high school graduates. The findings should therefore be replicated in patients with lower levels of education. The impact of education level on the reliability and validity of the scale should be examined.

Finally, the CUDOS-A was designed to assess the anxious distress specifier as defined in *DSM-5*. Studies of the impact of anxiety in depressed patients have examined categorical *DSM*-based anxiety disorders or dimensional measures of the severity of symptoms of anxiety that are not identical to the symptoms used to define the *DSM-5* specifier. The *DSM-5* Mood Disorders Work Group did not indicate why an anxious distress specifier was needed. That is, what information does this specifier convey beyond what is already accounted for by the presence of a comorbid anxiety disorder? Nor did the Work Group cite data supporting the choice of items included in the definition of the specifier.[64] While this is not a methodological limitation of the present study because the CUDOS-A was developed to assess the *DSM-5* definition, it is important to recognize that the *DSM-5* definition of the anxious distress specifier was not empirically derived, has not been previously validated, and is of unknown incremental validity beyond the identification of a comorbid anxiety disorder.

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