

# Performance characteristics and clinical utility of diagnostic criteria proposals in bereaved treatment-seeking patients

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**Background.** Persistent complex bereavement disorder (PCBD) is a protracted form of grief included in DSM Section 3 indicating a need for more research. Two other criteria sets [prolonged grief disorder (PGD) and complicated grief (CG) disorder] are also currently in use by researchers. This study evaluates rates of diagnosis of each proposed criteria set in a clinical sample of bereaved individuals participating in clinical research.

**Method.** Two groups in which persistent grief was judged to be present or absent completed an assessment instrument that included items needed to diagnose PCBD as well as PGD and CG. One group included grief treatment-seeking participants in our multicenter National Institute of Mental Health (NIMH)-sponsored study who scored  $\geq 30$  on the Inventory of Complicated Grief (ICG) and the other comprised bereaved adults enrolled in clinical research studies who scored  $< 20$  on the ICG. Rates of diagnosis were determined for proposed PCBD, PGD and CG criteria.

**Results.** PCBD criteria diagnosed 70 [95% confidence interval (CI) 64.2–75.8] % of the grief treatment-seeking group, PGD criteria identified 59.6 (95% CI 53.4–65.8) % of these individuals and CG criteria identified 99.6 (95% CI 98.8–100.0) %. None of the three proposed criteria identified any cases in the bereaved comparison group.

**Conclusions.** Both proposed DSM-5 criteria for PCBD and criteria for PGD appear to be too restrictive as they failed to identify substantial numbers of treatment-seeking individuals with clinically significant levels of grief-related distress and impairment. Use of CG criteria or a similar algorithm appears to be warranted.

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**Key words:** Complicated grief, DSM-5 criteria, functional impairment, persistent complex bereavement disorder, stress.

## Introduction

The loss of someone close usually triggers a period of acute grief that is distressing and disruptive of ongoing life. Grief is not a mental disorder and most people adapt to loss and regain the capacity to function effectively in the world (Zisook & Shear, 2009). However,

considerable evidence now exists that some bereaved people, estimated to be about 7%, experience a response to loss in which acute grief persists and remains intense and impairing (Kersting *et al.* 2011). A proposal was made to include complicated grief (CG) as a stress response syndrome in the Diagnostic and Statistical Manual of Mental Disorders at the time of development of the fourth edition (DSM-IV) (Marwit, 1991). At that time, the proposal was not accepted because of lack of sufficient empirical work on its constituent elements (Horowitz *et al.* 1997). Since then there has been considerable further research on this topic, much of it stimulated by landmark papers from Prigerson *et al.* (1995a, b, 1999). Considerable evidence

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indicates the presence of an identifiable syndrome of protracted impairing grief across cultures (e.g. Nakajima *et al.* 2009; Shear *et al.* 2011), following differing circumstances of death (Shear *et al.* 2011) and different relationships with the deceased (e.g. Meert *et al.* 2011), and with specificity of treatment response (Shear, 2015; Shear *et al.* 2016).

In preparation for the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5), the Trauma and Stress Disorders Work Group again deliberated about whether to include a new syndrome of persistent impairing grief in DSM-5. The workgroup considered two main proposals for diagnostic criteria along with undertaking a thorough review of the literature. One diagnostic proposal identified a condition named prolonged grief disorder (PGD) that was developed using data from a community survey consisting of 291 bereaved individuals, 28 of whom were considered to have PGD (Prigerson *et al.* 2009). The other proposal retained the name complicated grief (CG) and was based upon data from a clinical sample (Shear *et al.* 2011) of 665 bereaved individuals, 288 of whom were considered to have CG (Simon *et al.* 2011).

Both diagnostic criteria proposals were developed from data collected using a version of the Inventory of Complicated Grief (ICG), a widely used well-validated measure with excellent psychometric properties (Prigerson *et al.* 1995b). As a result, criteria sets proposed for PGD and CG have many symptoms in common but they are not identical (Prigerson *et al.* 2009; Shear *et al.* 2011). Ultimately the DSM-5 work group proposed the inclusion of a potential new disorder they named persistent complex bereavement disorder (PCBD) that bears some resemblance to both PGD and CG criteria. They placed a proposed criteria set within Section 3 as an indication of the need for further study.

Our group has conducted three separate National Institute of Mental Health (NIMH)-funded clinical trials that demonstrated specificity of treatment response in these patients. In the absence of a 'gold standard', we identified study participants using a score above the published and widely accepted cut-score on a well-validated grief symptom measure (ICG; Prigerson *et al.* 1995b) and confirmation on a clinical interview that grief was the most important problem in need of treatment. Valid diagnostic criteria would both diagnose all such cases with protracted impairing grief ('true positives') and not diagnose bereaved individuals who do not have such symptoms.

In order to provide guidance about criteria for the next iteration of the DSM (First, 2016) we need to determine how different proposed criteria perform in clinical samples. To do so we undertook a study to compare rates of diagnosis by proposed PGD, CG and PCBD criteria in

our bereaved treatment study participants with persistent impairing grief as well as a sample of bereaved individuals participating in clinical research studies that were not grief-focused. The purpose of this paper is to describe this study and its results.

## Method

### Study design

The current study utilized data collected in two NIMH-funded treatment studies. Both studies included a structured clinical interview that included all symptoms proposed by each of the three criteria sets and administered by a rater trained to reliability but unaware that the data were being used to compare the three diagnostic criteria sets. In addition, to examine the possibility of over-diagnosis we further constituted a comparison group of bereaved participants enrolled in ongoing clinical research studies for whom grief-related problems were not considered to be the primary problem. All participants signed informed consent for participation in the assessment protocol.

### Study participants

Grief treatment-seeking participants bereaved for at least 6 months ( $n = 240$ ) were recruited at a university-based psychiatric research clinic at Columbia University ( $n = 70$ ), Massachusetts General Hospital ( $n = 58$ ), University of Pittsburgh Medical Center ( $n = 55$ ) or University of California San Diego ( $n = 57$ ). Study participants were screened by telephone using the Brief Grief Questionnaire (Shear *et al.* 2006) and underwent a baseline assessment in person. Those who met inclusion and no exclusion criteria were randomly assigned to receive study treatment in our collaborative treatment study (MH60783; MH85288; MH85308; MH85297:  $n = 189$ ) (Shear *et al.* 2016) or a study for older adults (MH70741:  $n = 51$ ) (Shear *et al.* 2014). Assessments were completed between March 2010 and September 2014.

Treatment study participants met our treatment study inclusion criteria including a score  $\geq 30$  on the ICG (Prigerson *et al.* 1995b) and a judgment that grief was the primary problem in need of treatment. For the current study we included participants bereaved  $\geq 12$  months who responded affirmatively to the question 'Overall, is grief interfering a lot with your ability to work or socialize or function in other ways?'

Treatment study exclusion criteria included current substance use disorder (past 6 months), lifetime history of psychotic disorder, bipolar I disorder, cognitive impairment [Montreal Cognitive Assessment (Nasreddine *et al.* 2005) score  $< 21$  or the Mini-Mental State (Folstein *et al.* 1975) score  $< 24$ ], active suicidal ideation requiring

**Table 1.** Items used to diagnose PCBD and comparison items for PGD and CG

	PCBD DSM-5 (2013)	PGD	CG
Criterion A	Loss > 12 months earlier	Loss > 6 months earlier	Loss > 6 months earlier
Criterion B	One of these: Yearning – Intense sorrow Preoccupation with the deceased Preoccupation with the death	Required: Yearning	One of these: Yearning Intense loneliness Life is unbearable Insistent thoughts of the deceased
Criterion C	At least six of 12: Avoid reminders Mistrust of others Bitterness/anger (Disbelief/numbness) Role confusion Difficulty accepting Difficulty making plans – (Disbelief/numbness) – – – – Difficulty positive reminiscing Self-blame Desire to die Feel alone/detached	At least five of 9: Avoid reminders Mistrust of others Bitterness/anger Numbness Role confusion Difficulty accepting Difficulty moving on Stunned or shocked – Life unfulfilling – – – – – – – – –	At least two of 8: Avoid reminders or seek to feel close Mistrust of others Bitterness/anger (Shocked or numb) – – (Shocked or numb) Disbelief – Troubling thoughts Hear/see deceased Strong reactivity to reminders – – – – –

PCBD, Persistent complex bereavement disorder; PGD, prolonged grief disorder; CG, complicated grief; DSM-5, Diagnostic and Statistical Manual of Mental Disorders, fifth edition.

hospitalization, concurrent psychotherapy, or pending lawsuit or disability claim related to the death.

A comparison group of bereaved participants was constituted from other ongoing research studies at the Latelife Depression Prevention and Treatment Center (P30 MH90333) at the University of Pittsburgh Medical Center ( $n = 62$ ) or The Center for Anxiety and Traumatic Stress Disorders at the Massachusetts General Hospital ( $n = 24$ ). For these participants, a mood or anxiety disorder was the primary diagnosis established using a structured clinical interview for DSM-IV and all scored <20 on the ICG. These assessments were completed between April and August 2014.

#### Assessment instruments

Treatment study participants completed a structured clinical interview and self-report measures of symptom severity and impairment, and provided demographic and loss-related information. Bereaved participants from other studies completed a grief symptom severity measure and a self-report version

of our structured clinical interview as well as demographic information and more limited loss-related information.

The Structured Clinical Interview for Complicated Grief (SCI-CG) is a 31-item clinical interview that uses SCID-like scoring (1 = 'absent', 2 = 'unsure or equivocal', 3 = 'present') and includes symptoms needed to evaluate all three proposed criteria sets (see Table 1). The SCI-CG has good internal consistency (Cronbach's  $\alpha = 0.76$ ) and test-retest reliability (intraclass correlation = 0.68) (Bui et al. 2015). Cronbach's  $\alpha$  for the self-report version is 0.81. Copies of the instrument can be obtained ([www.complicatedgrief.columbia.edu](http://www.complicatedgrief.columbia.edu)). Table 3 shows how the SCI-CG items map onto each of the criteria for PCBD; the mapping of SCI-CG items to criteria for PGD and CG is in online Supplementary Tables S1 and S2.

The ICG is a 19-item self-report questionnaire. Each item is rated on a five-point scale, with responses ranging from 0 = 'not at all' to 4 = 'severe'. The ICG is a well-validated self-report measure of grief symptoms with prior evidence for good internal consistency (Cronbach's  $\alpha = 0.94$ ) and test-retest reliability (intraclass correlation = 0.80) (Prigerson et al. 1995b).

**Table 2.** Demographic, loss-related and clinical characteristics of the study samples

	Grief treatment-seeking sample (n = 240)		Comparison sample (n = 86)		Test statistic (df) <sup>a</sup>	p
Gender: female, n (%)	191	(79.6)	60	(69.8)	3.4 (1)	0.0635
Mean age, years (s.d.)	54.6	(14.1)	22.5	(61.3)	2.6 (109.6)	0.0109
Race: white, n (%)	204	(85.0)	69	(80.2)	1.06 (1)	0.3039
Ethnicity: Hispanic, n (%)	27	(11.3)	–			
Employed, n (%)						
Employed or homemaker	137	(57.1)	–			
Retired	54	(22.5)	–			
Unemployed	49	(20.4)	–			
Marital status, n (%)					7.7 (3)	0.053
Never married	62	(25.8)	22	(25.6)		
Married	46	(19.2)	26	(30.2)		
Divorced/separated	39	(16.3)	17	(19.8)		
Widowed	93	(38.8)	21	(24.4)		
Median time since loss, years (range) <sup>b</sup>	3.4	(1–45.3)	12.9	(1–69.3)	7.9 (N.A.)	<0.0001
Person who died, n (%)					33.1 (3)	<0.0001
Partner of the bereaved person	98	(40.8)	15	(17.4)		
Parent of the bereaved person	70	(29.2)	38	(44.2)		
Child of the bereaved person	43	(17.9)	6	(7.0)		
Other relative or friend	29	(12.1)	27	(31.4)		
Type of death, n (%)					12.1 (1)	0.0005
Non-violent	170	(70.8)	77	(89.5)		
Violent	70	(29.2)	9	(10.5)		
Mean ICG score, range 0–76 (s.d.)	44.4	(9.2)	8.5	(6.3)	–39.6 (219.0)	<0.0001
Mean WSAS score, range 0–40 (s.d.)	23.2	(8.6)	0.8	(2.4)	–32.9 (239.2)	<0.0001

df, Degrees of freedom; s.d., standard deviation; N.A., not applicable; ICG, Inventory of Complicated Grief; WSAS, Work and Social Adjustment Scale.

<sup>a</sup> The two samples were compared using two-sample *t* tests (continuous variables) and  $\chi^2$  tests (categorical variables).

<sup>b</sup> Due to skewness, time since the loss was compared using a Wilcoxon rank sum test instead of a two-sample test.

The Work and Social Adjustment Scale (WSAS) is a self-report questionnaire rating grief-related impairment in work, home management, social leisure, private leisure, and in maintaining close relationships. Each item is scored on an eight-point scale ranging from 0 = 'no impairment' to 8 = 'very severe impairment'. The scale has previously reported good internal consistency (Cronbach's  $\alpha = 0.8$ ) and test-retest reliability (intraclass correlation = 0.73) across different disorders (Mundt *et al.* 2002).

#### Comparing diagnostic criteria sets for PCBD, PGD and CG

All three proposed criteria sets are designed to identify a syndrome of protracted impairing grief and include many similar symptoms. The three proposed criteria sets all require that the person be bereaved (criterion A). Each has a criterion B including yearning and a criterion C including bitterness or anger, mistrust of others, avoidance of reminders of the loss and other symptoms.

The three proposals differ in how criterion B and C are established. For criterion B, PCBD and CG require endorsement of either yearning or preoccupation with the deceased or intense emotional pain. PGD requires that the person has the presence of yearning. For criterion C, PCBD requires endorsement of 6 of 12 symptoms, PGD requires 5/9 and CG requires 2/8 symptoms.

#### Statistical analysis

We compared the CG treatment-seeking sample with bereaved participants in other clinical research studies on demographic, loss-related and clinical characteristics using two-sample *t* tests for continuous variables and  $\chi^2$  tests for categorical variables. A two-sided *p* value less than  $\alpha = 0.05$  was considered statistically significant.

We examined validity by determining the proportion of cases diagnosed by each criteria set in each of the two bereaved samples. This was done by dividing the number of participants diagnosed by the total

number of participants in the relevant study sample. The 95% confidence intervals (CIs) were computed using the standard formula for binomial proportions. All analyses were carried out using SAS 9.4 (SAS Institute, Inc., USA).

## Results

Demographic, loss-related and clinical characteristics of the CG and non-CG samples are given in Table 2. In addition to significantly lower scores on grief symptoms and impairment, the two samples differed significantly on most demographic and loss-related variables. The comparison sample was, on average, nearly 7 years older than the grief treatment-seeking sample, more likely to be married and less likely to be widowed. The death had occurred, on average, almost 10 years earlier. The target loss for the former group was more likely to be a parent or another relative or friend, and less likely to be a partner or their child. The death was also less likely to be violent.

### PCBD criteria

The rate of PCBD diagnosis in our grief treatment study participants was 70.0 (95% CI 64.2–75.8) %. Table 3 shows rates of endorsement of each criterion as well as each individual item. Among this sample, 95.8% met criterion B and 72.5% met criterion C. Three items were endorsed by less than 50% of participants: difficulty with positive reminiscing, desire to die in order to be with the deceased, and difficulty trusting others. None of the participants in the comparison group of bereaved individuals without evidence of protracted grief was diagnosed using the PCBD criteria. Fewer than 5% met criterion B and none met criterion C.

### PGD criteria

The rate of diagnosis of PGD in grief treatment study participants was 59.6 (95% CI 53.4–65.8) %. About 10% of those not diagnosed with PGD failed to endorse yearning (criterion B) and 66% failed to meet criterion C. None of the bereaved individuals in the comparison group was diagnosed using the PGD criteria. Only 2% endorsed criterion B and none endorsed criterion C.

### CG criteria

Virtually all of the treatment study sample (99.6%, 95% CI 98.8–100.0%) were diagnosed using the CG proposed criteria. All but one participant endorsed criterion B and all endorsed criterion C. None of the bereaved comparison group was diagnosed using CG

criteria. Only 6% endorsed criterion B and 5% endorsed criterion C.

### Clinical characteristics of treatment study participants not meeting criteria for PCBD and PGD

In order to examine whether treatment study participants not diagnosed using PCBD or PGD criteria were borderline or mild in severity, we examined mean scores on the ICG and WSAS. Although scores on these grief-related symptom and impairment measures were higher in those diagnosed compared with not diagnosed for both PCBD or PGD criteria, mean scores on both instruments were well above thresholds for clinical significance in those not meeting the proposed criteria. Mean ICG score for participants not diagnosed using PCBD was 39.9 (s.d. = 6.8) and mean WSAS score was 21.0 (s.d. = 7.8). For those not meeting criteria for PGD, the mean ICG score was 40.7 (s.d. = 7.1) and the mean WSAS score was 21.8 (s.d. = 8.2).

## Discussion

A protracted form of grief causing substantial impairment in functioning has been identified for more than two decades (e.g. Horowitz *et al.* 1997), during which time numerous studies have documented its role as a significant and treatable public health problem (Simon, 2013; Shear, 2015; Bui *et al.* 2015). As of DSM-5, this condition is included as a stress response syndrome and provisional criteria for a syndrome called ‘persistent complex bereavement disorder’ are included in Section 3. We evaluated rates of diagnosis using PCBD criteria among individuals seeking treatment for protracted grief and assessed using rigorous clinical research procedures and found that only 70% of this group met these criteria. Rates of diagnosis were similarly low using PGD criteria (60%). By contrast, proposed CG criteria diagnosed virtually all of these individuals. None of the three proposed criteria sets diagnosed bereaved individuals with low grief levels. We conclude that revisions are needed in proposed DSM-5 criteria and that CG but not PGD criteria could be an alternative.

A recent report from the community-based National Military Family Bereavement Study found results virtually identical to ours. PCBD criteria identified 55% of individuals who score  $\geq 30$  on the ICG and  $\geq 20$  on the WSAS and PGD criteria diagnosed 60%. CG criteria diagnosed 98% of cases. All three criteria sets identified less than 2% of the bereaved military family survey population that scored  $< 20$  on the ICG (Cozza *et al.* 2016). The military family sample was comprised primarily of younger adults (mean age 47.3 years) and

**Table 3.** Persistent complex bereavement disorder item endorsement and conditional probability of diagnosis

	SCI-CG item match	Treatment study participants (n = 240)	Bereavement comparison group (n = 86)
Overall		168 (70.0)	0 (0.0)
B: Since the death, at least one symptom experienced on more days than not and persisted to:		230 (95.8)	4 (4.7)
1. Persistent yearning/longing for deceased	2	215 (89.6)	2 (2.3)
2. Intense sorrow and emotional pain in response to death	3	208 (86.7)	0 (0.0)
3. Preoccupation with the deceased	4	176 (73.3)	2 (2.3)
4. Preoccupation with the circumstances of the death	6	161 (67.1)	1 (1.2)
C: Since the death, at least six of following symptoms experienced more days than not, and have persisted for at least 12 months:		174 (72.5)	0 (0.0)
1. Marked difficulty accepting death	7	138 (57.5)	0 (0.0)
2. Experiencing disbelief or emotional numbness	8, 9	173 (72.1)	0 (0.0)
3. Difficulty with positive reminiscing about the deceased	10	52 (21.7)	1 (1.2)
4. Bitterness of anger related to death	11	186 (77.5)	2 (2.3)
5. Maladaptive appraisals about oneself in relation to the deceased or the death (e.g. self-blame)	12	154 (64.2)	1 (1.2)
6. Excessive avoidance of reminders of the loss	14	172 (71.7)	0 (0.0)
7. A desire to die in order to be with the deceased	22	43 (17.9)	0 (0.0)
8. Difficulty trusting other individuals since the death	24	104 (43.3)	0 (0.0)
9. Feeling alone or detached from other individuals since the death	25	160 (66.7)	2 (2.3)
10. Feeling that life is meaningless or empty without the deceased, or the belief that one cannot function without the deceased	28	148 (61.7)	0 (0.0)
11. Confusion about one's role in life, or a diminished sense of one's identity	30	143 (59.6)	0 (0.0)
12. Difficulty or reluctance to pursue interests since the loss or to plan for the future	31	148 (61.7)	0 (0.0)

Data are given as number of participants (percentage endorsing).  
SCI-CG, Structured Clinical Interview for Complicated Grief.

almost all were bereaved by violent means. It is striking that results match closely those in our clinical sample comprised of older adults who were primarily bereaved by natural causes. There was no evidence in either the military family study or in our clinical treatment-seeking sample that individuals not diagnosed by PCBD or PGD criteria have mild or borderline symptoms and might be better characterized as having normal grief.

Research findings indicating specificity of treatment response for a condition are important data that support a need for diagnostic criteria. Results of three NIMH-funded treatment studies show response specificity for grief symptoms when compared with proven efficacious treatments for depression. It is important that diagnostic criteria have a high rate of case identification when applied to this treatment-responsive clinical

sample. We found that only CG criteria and not PCBD or PGD criteria produced rates of case identification sufficient to be of clinical utility.

To place our observations within a global public health context, we note that the World Health Organization is preparing a new version of the 11th revision of the International Classification of Diseases (ICD-11). Their Workgroup on Trauma and Stress Disorders proposed a new diagnosis called prolonged grief disorder (Maercker *et al.* 2013; Luciano, 2015); however, they did not propose use of PGD criteria. Rather the description of this condition closely resembles proposed CG criteria. We did not include a test of the ICD-11 proposal because unlike DSM-5, ICD-11 provides only a list of common symptoms and no accompanying algorithm making it difficult to evaluate systematically the performance characteristics of

the ICD-11 proposal. That said, the proposed ICD guidelines for this condition have high face validity and clinical credibility.

Our analyses are limited by the fact that our treatment study participants were recruited from clinical research settings and may not be generalizable to all help-seeking individuals with persistent impairing grief. However, this sample is among the clinical population that diagnostic criteria need to identify as appropriate for specific treatment. Moreover, findings reported by Cozza et al. (2016) from a large community survey of bereaved military family members show case identification rates for the three criteria sets that are very similar to those that we found. The fact that none of the criteria sets diagnosed individuals in either study who endorsed low scores on grief-related symptom and impairment supports the likelihood of high specificity of all three proposals.

Another important limitation of this study is the absence of a 'gold standard' for diagnosing the condition in question. However, this limitation is unavoidable for a condition for which there are not yet validated or agreed-upon criteria. In the absence of such a standard, we used a rigorous reliable assessment procedure. We required a score above the published and widely accepted cut-score on a well-validated symptom measure (ICG; Prigerson et al. 1995b), significant bereavement-related distress and impairment persisting at least 12 months after the death of a loved one and confirmation that grief was the most important problem in need of treatment.

In summary, conservative prevalence estimates suggest about 3% of the general population (7% of bereaved individuals) are affected by the condition named by DSM-5 as persistent complex bereavement disorder (Kersting et al. 2011). It is likely that tens of millions of people are suffering in this way. Our studies have documented the efficacy of a well-specified grief-targeted treatment for these individuals (Shear et al. 2005, 2014, 2016). Currently, diagnostic criteria are not finalized and clinicians may be uncertain about how to identify patients in need of grief-focused treatment. Papers in the literature utilize different diagnostic procedures and this situation is not optimal for clinical care or for optimizing what we can learn from research findings. Our study is the second to show differential sensitivity of the three main proposed criteria sets in identifying individuals with high levels of grief-related symptoms and impairment. Specifically both studies suggest that PCBD criteria are not adequately sensitive, failing to diagnose a high proportion of help-seeking individuals who show a specific treatment response to grief-targeted intervention. This problem could be solved in several ways. For example, the proposed CG criteria set could be used. Decision rules for PCBD or PGD criteria could be modified or a

new group of symptoms and decision rules could be developed and tested. However it is done, there is a pressing need to establish criteria that can be used to identify a large group of individuals experiencing grief-related distress and impairment and responsive to a well-specified targeted intervention.

### Supplementary material

The supplementary material for this article can be found at <https://doi.org/10.1017/S0033291716002749>

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### Declaration of Interest

C.M. reports no competing interests. M.K.S. reports a contract with Guilford Press to write a book on grief. C.F.R. reports no competing interests. N.M.S. reports grant funding from the American Foundation for Suicide Prevention, Department of Defense, NIH, Janssen Pharmaceuticals and Highland Street Foundation and support for speaking, participating in continuing medical education for the Massachusetts General Hospital Psychiatry Academy. S.Z. reports no competing interests. N.S. reports no competing interests. Y.W. reports no competing interests. B.L. reports no competing interests. N.D. reports no competing interests. M.B.F. reports serving as faculty of the Lundbeck International Neuroscience Foundation. A.G. reports no competing interests. C.G. reports no competing interests. K.G. reports no competing interests.

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