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ORIGINAL ARTICLE

Validation of the Brazilian Portuguese version of the Premenstrual Symptoms Screening Tool (PSST) and association of PSST scores with health-related quality of life

Rachel de A. Câmara, ¹ Cristiano A. Köhler, ¹ Benicio N. Frey, ^{2,3,4} Thomas N. Hyphantis, ⁵ André F. Carvalho ¹

¹Departamento de Clínica Médica e Grupo de Pesquisa em Psiquiatria Translacional, Faculdade de Medicina, Universidade Federal do Ceará (UFC), Fortaleza, CE, Brazil. ²MiNDS Neuroscience Graduate Program, McMaster University, Hamilton, ON, Canada. ³Mood Disorders Program and Women's Health Concerns Clinic, St. Joseph's Healthcare, Hamilton, ON, Canada. ⁴Department of Psychiatry and Behavioral Neurosciences, McMaster University, Hamilton, ON, Canada. ⁵Department of Psychiatry, Division of Medicine, School of Health Sciences, University of Ioannina, Greece.

Objective: To develop and validate a Brazilian Portuguese version of the Premenstrual Symptoms Screening Tool (PSST), a questionnaire used for the screening of premenstrual syndrome (PMS) and of the most severe form of PMS, premenstrual dysphoric disorder (PMDD). The PSST also rates the impact of premenstrual symptoms on daily activities.

Methods: A consecutive sample of 801 women aged ≥ 18 years completed the study protocol. The internal consistency, test-retest reliability, and content validity of the Brazilian PSST were determined. The independent association of a positive screen for PMS or PMDD and quality of life determined by the World Health Organization Quality of Life instrument-Abbreviated version (WHOQOL-Bref) was also assessed.

Results: Of 801 participants, 132 (16.5%) had a positive screening for PMDD. The Brazilian PSST had adequate internal consistency (Cronbach's alpha = 0.91) and test-retest reliability. The PSST also had adequate convergent/discriminant validity, without redundancy. Content validity ratio and content validity index were 0.61 and 0.94 respectively. Finally, a positive screen for PMS/PMDD was associated with worse WHOQOL-Bref scores.

Conclusions: These findings suggest that PSST is a reliable and valid instrument to screen for PMS/ PMDD in Brazilian women.

Keywords: premenstrual dysphoric disorder; mood disorders; quality of life; premenstrual symptoms screening tool; psychiatry

Introduction

Female reproductive life events are often accompanied by physical and psychological challenges associated with a negative impact on women's functioning. One such example is premenstrual syndrome (PMS), a cluster of recurrent physical, psychological, and emotional symptoms occurring during the late luteal phase and disappearing within a few days of the onset of menses. As many as 80% of women experience at least one of the PMS symptoms 5.5 described in the ICD-10, which include, but are not limited to, mild psychological discomfort, feelings of bloating and weight gain, breast tenderness, swelling of

hands and feet, various aches and pains, poor concentration, sleep disturbances, and changes in appetite.

Moderate to severe PMS affects 20-35% of women and may cause significant functional impairment and deterioration of interpersonal relationships. 1 In turn, the prevalence of premenstrual dysphoric disorder (PMDD), the most severe form of PMS, has been estimated to vary from 3-8% among women of reproductive age. PMDD is a cyclical disorder closely related to the menstrual cycle. disappearing during pregnancy and after menopause.8 PMDD has deleterious effects on quality of life (QOL), 9-12 with a burden similar to that of dysthymia or major depressive disorder. ^{13,14} The definition of PMDD in both DSM-IV and DSM-5 is based upon a peri-menstrual pattern of at least one among four key affective symptoms (markedly depressed mood, feelings of hopelessness, or self-deprecating thoughts; marked anxiety, tension; marked affective lability; persistent anger or irritability, increased interpersonal conflicts) along with four out of seven additional physical or behavioral symptoms. 15 Per DSM-5, these manifestations must have occurred during

Correspondence: André F. Carvalho, Departmento de Clínica Médica, Faculdade de Medicina, Universidade Federal do Ceará (UFC), Rua Prof. Costa Mendes, 1608, 4° andar, CEP 60430-040, Fortaleza, CE, Brazil.

E-mail: andrefc7@hotmail.com

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most menstrual cycles in the past year to meet diagnostic criteria for PMDD. 15

Identification of PMS/PMDD has traditionally relied on prospective daily charting of symptoms over two consecutive symptomatic cycles. 16 However, this approach is timedemanding and may have reduced compliance, since a significant proportion of women refuse or do not properly fill the charts. 17,18 In addition, neither the DSM-IV nor the latest DSM-5 provide a set criteria or specifiers to determine PMDD severity. 19 To fill that gap, Steiner et al. 16 have developed the Premenstrual Symptoms Screening Tool (PSST). The PSST is a guick and clinician-friendly selfreport screening instrument for PMS/PMDD which also rates the impact of premenstrual symptoms on daily activities. This tool can identify women who meet full DSM-IV criteria for PMDD as well as women who experience PMS but do not qualify for a diagnosis of PMDD. Therefore, the PSST identifies women who would benefit from a more in-depth diagnostic interview for the diagnosis of PMDD, without the need to monitor symptoms over two reproductive cycles.16

The PSST has been translated into and/or validated in several languages, including Spanish,²⁰ Persian,²¹ German,^{22,23} Thai,²⁴ Chinese,²⁵ and Finish.²⁶ In the present study, we set out to develop and validate a Brazilian Portuguese version of this instrument, including content validity, internal consistency, and test-retest reliability. In addition, we investigated the usefulness of the PSST as a severity measure and examined the relation between PSST scores and health-related QOL.

Methods

Sample selection

We selected a convenience sample of 896 women from Fortaleza (state of Ceará), Brazil, who either worked as health professionals at Hospital Universitário Walter Cantídio or were currently enrolled in psychology, nursing, or medical programs at three universities: Universidade Federal do Ceará (UFC), Universidade de Fortaleza (UNIFOR), and Centro Universitário Christus (UniChristus). The exclusion criteria were: 1) refusal to participate in the study; 2) use of psychotropic medications in the past two months; 3) absence of menses (i.e., pregnancy or menopause); and 4) being younger than 18 years of age. Data were collected from July to December 2014. A sub-sample of 131 women from the initial sample repeated the PSST 30 days after the first assessment for calculation of test-retest reliability.

Development of the Brazilian Portuguese version of the Premenstrual Symptoms Screening Tool (PSST)

Initially the PSST was translated from English into Brazilian Portuguese in three steps: 1) English to Portuguese translation (by RAC); 2) comparison of the translated version with the original by a research psychiatrist fluent in English (by AFC); and 3) back-translation to English to assess item equivalence (by CAK). Next, the PSST underwent semantic validation in order to verify

comprehension of the items by subjects from the target population. Face validity was also verified at this stage. The questionnaire was then applied to a pilot sample of 10 women with different educational backgrounds. Words and terms deemed as ambiguous and/or difficult to comprehend by respondents were fixed. Finally, the PSST was revised and the final Brazilian Portuguese version was obtained (online-only supplementary material).

Instruments and procedures

The PSST consists of 19 items subdivided into two domains: the first domain comprises the 14 DSM-IV physical and psychological manifestations of PMS/PMDD, while the second domain is composed of five items assessing the functional impact of premenstrual symptoms. 16 Each item is rated according to a 4-point Likert scale (0 = absent; 1 = mild; 2 = moderate; 3 = severe). The symptoms included in the first domain are: anger/irritability. anxiety/tension, tearful, depressed mood/hopelessness. decreased interest in work, decreased interest in home, decreased interest in social activities, difficulty concentrating, fatigue/lack of energy, overeating/food cravings, insomnia, hypersomnia, feeling overwhelmed, and physical symptoms (breast tenderness, headaches, joint/ muscle pain, bloating, weight gain). The second domain rates the impact of these symptoms on work efficiency or productivity, relationships with coworkers, relationships with family, social life activities, and home responsibilities. A positive screen for PMDD according to the PSST requires: 1) the presence of at least five symptoms from the first domain, rated as moderate to severe; 2) at least one of the first four core symptoms (anger/irritability; anxiety/tension: tearful/increased sensitivity to rejections: and depressed mood/hopelessness) must be rated as severe; and 3) severe functional impact of endorsed premenstrual manifestations. A positive screen for PMS is established by the following criteria: 1) at least five of the premenstrual symptoms of the first domain rated as moderate to severe; 2) presence of at least one of the first four symptoms rated as moderate or severe; and 3) at least one item of the second domain rated as moderate or severe. Participants that do not fulfill any of these three criteria are classified as no/mild PMS. This was the classification adopted in this study. This cutoff for positive screening was originally recommended by the developers of the PSST, 16 and has been followed by other investigators. 21,23

Depressive symptoms were measured using the Brazilian Portuguese-validated Patient Health Questionnaire-9 (PHQ-9). PHQ-9 is a self-report questionnaire that employs the nine DSM-IV symptom-criteria for diagnosis of major depressive episodes. A total PHQ-9 score \geq 10 indicates a major depressive episode. The total PHQ-9 score can be used to classify the severity of the depressive episode (minimal, mild, moderate, moderately severe, or severe depression). Cronbach's alpha coefficient for the PHQ-9 in our sample was 0.80.

Anxiety symptoms were measured using the Brazilian Portuguese-validated version of the Beck's Anxiety Inventory (BAI). ^{29,30} BAI comprises 21 self-rating items scored in a Likert scale from 0 to 3, assessing the burden

of each anxiety manifestation in the week preceding the test. A final score is obtained by summing up the scores obtained for all items. The final score was used to classify anxiety severity in three categories (low, moderate, or high). Cronbach's alpha coefficient for the BAI in the present sample was 0.90.

Health-related QOL was assessed using the Brazilian Portuguese-validated version of the World Health Organization Quality of Life instrument-Abbreviated version (WHOQOL-Bref). The WHOQOL-Bref is a generic instrument covering 26 items assessing QOL in four dimensions: physical, psychological, social, and environment. Each item is rated on a five-point Likert scale and the scores are transformed on a scale from 0 to 100. A higher WHOQOL-Bref score indicates better QOL. Cronbach's alpha coefficients for the present sample ranged from 0.61 to 0.76 for the subscales and 0.85 for the whole instrument.

The study protocol was approved by the hospital's research ethics committee (321.019). All eligible subjects signed a written informed consent prior to study entry.

Statistical analysis

All analyses were carried out using SPSS version 22.0. Continuous variables are presented as either means \pm standard deviations (SD) or as medians. The Kolmogorov-Smirnov test was used to test the distribution of variables. Normally distributed continuous variables were compared using analysis of variance (ANOVA), whereas non-normally distributed continuous variables were compared using the Kruskal-Wallis test. Categorical variables are presented as frequencies (%), and were compared using Pearson's chisquare (χ^2) or Fisher's exact test as appropriate.

Convergent and discriminant (i.e., construct) validity was assessed based on Spearman's correlations between the scores of the Brazilian Portuguese version of the PSST and the PHQ-9 or BAI. Content validity was determined using qualitative and quantitative methods. through a panel of 10 experts (academic psychiatrists with experience in the care of women with PMDD). For qualitative content validity, experts were asked to provide comments on each item of the PSST regarding Brazilian Portuguese grammar, wording, scaling, and item allocation, as well as the accuracy, clarity, style and relevance of the translation. Qualitative content validity was determined by the content validity index (CVI) and content validity ratio (CVR). To compute the CVR, members of the expert panel were asked to rate each item as "essential," "useful, but not essential," or "not necessary." Then, the CVR was calculated to assess how pertinent each item was.33 To compute the CVI, members of the expert panel were asked to rate each PSST item in terms of relevance. clarity, and simplicity on a Likert scale from 1 to 4. The CVI for each item was computed as the number of experts assigning a rate of 3 or 4 to the item divided by the total number of experts. The overall PSST CVI and CVR values were obtained by averaging all items.34

The internal consistency of the PSST was measured using Cronbach's alpha coefficient, with a value $\geqslant 0.7$ considered satisfactory.³⁵ In addition, the correlation

between the two domains of the questionnaire was assessed by Spearman's rank correlation test. For the test-retest reliability we used intraclass correlation coefficients (random two-way model, absolute concordance) and Spearman's correlations between the total PSST scores measured twice in the same sample. Finally, the distribution of subjects in each diagnostic category between the two time points was assessed using the Wilcoxon signed-rank test.

The association of PMS symptoms with QOL was evaluated using one-way analysis of covariance (ANCOVA), adjusted by age, race, education, gross monthly income, and menstrual status. The Sidak test was used to control for multiple comparisons.

Results

Of our initial sample of 896 women, 801 answered the questionnaires and were included in the validation study (89.4% response rate). The mean \pm SD age of participants was 23.4 \pm 5.9 years. The mean \pm SD age at menarche was 12.1 \pm 1.4 years. Most participants (n=684; 85.4%) had no children. Menstrual cycle was regular in 602 participants (75.2%), and 281 (35.1%) were using hormonal contraceptives (HC).

As expected, most participants (n=351, 43.8%) had mild/no PMS, whereas 318 (39.7%) had moderate to severe PMS. PMDD screening was positive in 132 (16.5%) women (PMDD group).

Of all factors studied (Table 1), only menstrual status was associated with PMS/PMDD status: more women in the no/mild PMS group reported regular menstrual cycles, whereas more participants from the moderate to severe PMS group had irregular menstrual cycles. Only 602 (75.2%) women provided information about HC use. Use of HC was not associated with PMS/PMDD status, but more participants using HC reported regular menstrual cycles. PMS/PMDD status was not associated with age, number of children, education, race, marital status, religion, gross monthly income, or age at menarche (Table 1).

Construct validity

The Brazilian Portuguese version of the PSST showed adequate convergent/discriminant validity. There was some overlap of constructs, however without redundancy, as shown by the moderate correlations between PSST scores and measures of depression (PHQ-9) or anxiety (BAI) (Spearman's rho between 0.3 and 0.6; Table 2). Furthermore, more women in the PMS and PMDD groups scored positive for a major depressive episode according to the PHQ-9 (Table 3; $\chi^2=95.773,$ df = 2, p < 0.001, Pearson's χ^2 test). Similarly, the severity of depressive symptoms as measured by the PHQ-9 was associated with a positive screen of either PMS or PMDD according to the PSST (Table 3; $\chi^2=146.946,$ p < 0.001, Fisher's exact test). The severity of anxiety symptoms according to the BAI was also associated with the severity of PMS by the PSST (Table 3; $\chi^2=52.830,$ p < 0.001, Fisher's exact test).

	Valid n (total=801)	No/mild PMS (n=351)	PMS (n=318)	PMDD (n=132)	p-value
Age (years), mean (SD)/median	801	23.3 (5.5)/22.0	23.5 (6.3)/22.0	23.2 (6.4)/21.0	0.238*
Number of children					
None	749	299 (92.3)	272 (91.0)	113 (89.7)	0.882^{\dagger}
1-2		20 (6.2)	21 (7.0)	10 (7.9)	
≥ 3		5 (1.5)	6 (2.0)	3 (2.4)	
Years of education					
1-5	768	2 (0.6)	2 (0.7)	1 (0.8)	0.082 [†]
6-9		0 (0.0)	3 (1.0)	0 (0.0)	
10-12		25 (7.4)	23 (7.5)	18 (14.5)	
≥ 13		310 (92.0)	279 (90.9)	105 (84.7)	
Race					
Caucasian	787	141 (41.1)	137 (43.6)	48 (36.9)	0.494^{\dagger}
African descent		12 (3.5)	8 (2.5)	3 (2.3)	
Mulatto [‡]		170 (49.6)	155 (49.4)	75 (57.7)	
Asian		20 (5.8)	12 (3.8)	4 (3.1)	
Marital status					
Single	796	309 (88.8)	268 (84.8)	113 (85.6)	0.118 [†]
Married/stable union		36 (10.3)	46 (14.6)	15 (11.4)	
Divorced		3 (0.9)	2 (0.6)	4 (3.0)	
Religion					
Catholic	791	236 (67.6)	189 (60.6)	75 (57.7)	0.226 [†]
Evangelical (Protestant)		42 (12.0)	50 (16.0)	25 (19.2)	
Spiritualist		11 (3.2)	17 (5.4)	8 (6.2)	
Other		4 (1.1)	4 (1.3)	3 (2.3)	
No religion		56 (16.0)	52 (16.7)	19 (14.6)	
Gross monthly income					
< US\$ 319	739	69 (21.0)	47 (16.1)	22 (18.5)	0.442
US\$ 319-638		60 (18.3)	72 (24.7)	31 (26.1)	
US\$ 638-1,276		72 (22.0)	68 (23.3)	23 (19.3)	
US\$ 1,276-2,552		48 (14.6)	46 (15.8)	19 (16.0)	
≥ US\$ 2,552		79 (24.1)	59 (20.2)	24 (20.2)	
Menstrual status					
Regular	797	280 (80.0) ^{II}	226 (71.7) [¶]	96 (72.7)	0.034§
Irregular		70 (20.0) [¶]	89 (28.3) ¹¹	36 (27.3)	0.00
Hormonal contraception					
No	602	126 (50.2)	135 (54.4)	60 (58.3)	0.348§
Yes	302	125 (49.8)	113 (45.6)	43 (41.7)	3.0.10

Data presented as n (%), unless otherwise specified.

Content validity

The CVR and CVI were 0.61 and 0.94 respectively, which confirms that the Brazilian Portuguese version of the PSST has adequate content validity. The expert panel considered the Brazilian Portuguese version of the PSST adequate, and suggested minor changes.

Internal consistency reliability

The Brazilian Portuguese version of the PSST showed high internal consistency. Cronbach's alpha coefficient

was 0.91 overall, 0.87 for the first domain and 0.84 for the second domain. There was also a high degree of correlation between PSST domains and the PSST score (> 0.7; Table 2).

Test-retest reliability

The Brazilian Portuguese version of the PSST showed adequate test-retest reliability. In a sub-sample of 131 women, the intraclass correlation coefficient was 0.867 (95% confidence interval [95%CI] 0.812-0.906; p < 0.001) between the total PSST scores from two different

PMDD = premenstrual dysphoric disorder; PMS = premenstrual syndrome; SD = standard deviation.

^{*} Kruskal-Wallis test; † Fisher's exact test; § Pearson's chi-square test.

[‡]Refers to an ethnic group of mixed white and black ancestry.

Observed was higher than expected in this cell (adjusted residual > 2).

Observed was lower than expected in this cell (adjusted residual < -2).

^{**} One-way analysis of variance (ANOVA).

Table 2 Evaluation of convergent/discriminant validity of the Brazilian Portuguese version of the PSST

3	•		
Domain 1 (n=801)	Domain 2 (n=801)	PHQ-9 (n=783)	BAI (n=738)
0.979*	0.877* 0.766*	0.543* 0.536*	0.417* 0.419* 0.348*
	(n=801)	(n=801) (n=801) 0.979* 0.877*	(n=801) (n=801) (n=783) 0.979* 0.877* 0.543*

Data presented as Spearman's correlation coefficients between PSST scores and measures of depression and anxiety. BAI = Beck's Anxiety Inventory; PHQ = Patient Health Questionnaire; PSST = Premenstrual Symptoms Screening Tool. *p < 0.001.

	No/mild PMS	PMS	PMDD	p-value
PHQ-9 depression*				
Yes	41 (11.9) [†]	102 (32.8) [‡]	70 (55.1) [‡]	< 0.001
No	304 (88.1) [‡]	209 (67.2) [†]	57 (44.9) [†]	
PHQ-9 major depressive episode ^{II}				
Yes	9 (2.6) [†]	35 (11.3)	41 (32.3) [‡]	< 0.001
No	336 (97.4)‡	276 (88.7)	86 (67.7) [†]	
PHQ-9 other type of depression [¶]				
Yes	28 (8.1) [†]	37 (11.9)	27 (21.3) [‡]	< 0.001 [§]
No	317 (91.9)‡	274 (88.1)	100 (78.7)†	
PHQ-9 depression severity				
Minimal (0-4)	179 (51.9) [‡]	77 (24.8) [†]	16 (12.6) [†]	< 0.001*
Mild (5-9)	125 (36.2)	132 (42.4)‡	41 (32.3)	
Moderate (10-14)	38 (11.0) [†]	74 (23.8) [‡]	41 (32.3) [‡]	
Moderately severe (15-19)	3 (0.9)†	20 (6.4)	18 (14.2) [‡]	
Severe (20-27)	0 (0.0) [†]	8 (2.6)	11 (8.7) [‡]	
BAI anxiety severity				
Low (0-21)	318 (95.5) [‡]	252 (87.5) [†]	83 (70.9) [†]	< 0.001*
Moderate (22-35)	15 (4.5) [′]	28 (9.7)	24 (20.5)	
High (≥ 36)	0 (0.0) [†]	8 (2.8) [‡]	10 (8.5) [‡]	

Data presented as n (%).

BAI = Beck's Anxiety Inventory; PHQ = Patient Health Questionnaire; PMDD = premenstrual dysphoric disorder; PMS = premenstrual syndrome.

assessments performed a month apart. Furthermore, the correlation between total PSST scores in the two measurements was also high (Spearman's rho = 0.758, p < 0.001). Finally, there was no difference between the two assessments in the classification of women into one of the three PMS diagnostic categories (z = -0.384, p = 0.701 in Wilcoxon signed-rank test).

Association between PMS/PMDD and health-related QOL

The severity of premenstrual symptoms was associated with impaired QOL. WHOQOL-bref scores were available for only 697 (87.0%) participants due to missing data. After adjusting for age, race, education, gross monthly income, and menstrual status, the mean scores for the physical, psychological, and social domains decreased progressively as the severity of PMS increased (Figure 1).

The PMS and PMDD groups had similar impairment in environmental QOL.

Discussion

In the present study, a Brazilian Portuguese version of the PSST was developed. The resulting questionnaire displayed adequate internal consistency and test-retest reliability, as well as appropriate content and construct validities. The prevalence of PMDD, albeit relatively high (16.5%), is consistent with that reported in a previous study conducted in a sample of young female students with sociodemographic characteristics similar to our sample. To cal/cultural factors may account for such elevated number of PMDD-positive cases in Brazil. Nevertheless, the recommended cutoff score for the PSST¹⁶ might have resulted in a considerable number of

^{*} Defined as PHQ-9 score ≥ 10.

[†] Observed was lower than expected in this cell (adjusted residual < -2).

 $^{^{\}ddagger}$ Observed was higher than expected in this cell (adjusted residual > 2).

Pearson's chi-square test; ** Fisher's exact test.

Defined by the following criteria: a) \geq 5 of the 9 symptoms are present at least "more than half of the days"; b) 1 of the symptoms is depressive mood or anhedonia; and c) symptom 9 ("thoughts that you would be better off dead or hurting yourself in some way") is present regardless of frequency.

Defined by the following criteria: a) 2, 3, or 4 depressive symptoms are present at least "more than half of the days"; b) one of the symptoms is depressive mood or anhedonia; and c) symptom 9 is present regardless of frequency.

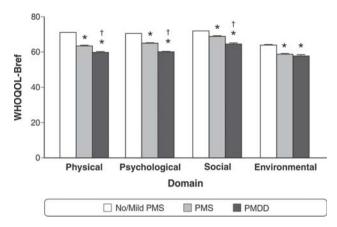


Figure 1 Greater PMS severity was associated with decreased health-related QOL.WHOQOL-bref was used to measure physical, psychological, social, and environment QOL domains. Data are presented as mean \pm standard error of mean (n=697). PMDD = premenstrual dysphoric disorder; PMS = premenstrual syndrome; QOL = quality of life; WHOQOL-bref = World Health Organization Quality of LifeBref. * p < 0.05 vs.no/mild PMS group and † p < 0.05 vs. PMS group (analysis of covariance [ANCOVA] adjusted for age, race, education, gross monthly income, and menstrual status).

false-positive cases. Thus, a positive screening for PMDD deserves subsequent diagnostic confirmation. It should also be noted that two differences in diagnostic criteria for PMDD have emerged in the DSM-5 in contrast to the DSM-IV. First, mood lability and irritability are listed first in the latter version. Furthermore, the DSM-5 incorporated the concept of distress in addition to impairment due to PMDD symptoms. ^{15,37} Therefore, more stringent cutoffs for PSST should be evaluated in future studies in contrast to a structured diagnostic interview validated by the DSM-5.

The correlations obtained in the present study between PSST and anxiety (BAI) as well as depressive symptom scores (PHQ-9) indicate that the PSST has adequate convergent/discriminant validity. In addition, the association of a positive screen for PMDD with a positive screen for a major depressive episode further suggests that the instrument has acceptable convergent validity. However, the use of the PHQ-9 as a parameter for convergent validity of the PSST deserves further investigation, and is arguably a limitation of the present study. We also found a "dose-response" association between the severity of PMS and all QOL domains, except environmental QOL. This result is in agreement with previous studies showing that severe PMS/PMDD symptoms negatively affect QOL. 10-12,38-40

Some limitations of the present study must be addressed. First, we relied on self-reported information to exclude women with any physical or psychiatric comorbidity. Second, a receiver operating characteristic (ROC) analysis of the Brazilian Portuguese version of the PSST was not performed in the present study. Therefore, future studies should use this tool combined with standard diagnostic practices (e.g., prospective daily charting) and with structured clinical interviews validated according to DSM-5 criteria. The main strengths of our study were the large

sample size and the use of well-established and validated anxiety, depression, and health-related QOL instruments.

Our findings suggest that the Brazilian version of PSST is reliable and can be used as a valid measure for the screening of PMS and PMDD in Brazilian women. Future studies measuring the ROC properties of the Brazilian Portuguese version of the PSST against a two-month prospective charting is necessary to confirm the relatively high prevalence of PMDD found in this Brazilian population.

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Disclosure

The authors report no conflicts of interest.

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