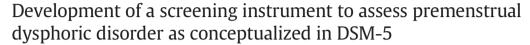
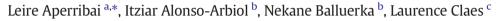


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ABSTRACT

Objective: This study aimed at developing and validating a screening instrument to assess premenstrual dysphoric disorder (PMDD) based on DSM-5 criteria, which is not yet available.

Methods: The Premenstrual Dysphoric Disorder Questionnaire for DSM-5 (*Cuestionario del Trastorno Disfórico Premenstrual – DSM-5*), a 25-item questionnaire to assess PMDD was developed and completed in Spanish by 2820 women (Age M = 23.43; SD = 7.87). Exploratory factor analysis (N = 1410) and confirmatory factor analysis (N = 1410) were performed in randomly selected subsamples. Empirical evidence of construct validity was obtained via a multitrait-multimethod approach (N = 118). Additional validity evidence was provided by associating PMDD with Neuroticism. Internal consistency and test–retest reliability were checked.

Results: Exploratory and confirmatory factor analyses yielded a bi-dimensional structure. The first dimension, called Dysphoria, included dysphoric symptoms and weight gain; the second dimension, Apathy, referred to apathetic and physical symptoms. Both dimensions displayed good internal consistency coefficients (Dysphoria's ordinal alpha = 0.88; Apathy's ordinal alpha = 0.84), and moderate temporal stability. The multitrait-multimethod analysis showed that convergent coefficients were higher than discriminant coefficients. Furthermore, a positive relationship between Neuroticism and PMDD was observed.

Conclusion: These findings suggest that the instrument is valid and reliable to assess PMDD.

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1. Introduction

Before the release of the fifth version of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) [1], premenstrual dysphoric disorder (PMDD) has been classified in DSM-IV-TR [2] as a Mood Disorder Not Otherwise Specified. According to DSM-IV-TR, 3-5% of women of menstrual age may suffer from the disorder. Of these women, 90.6% consider the symptoms to be normal (not pathological) and 18.7% seek professional help, although in some cases they receive an inadequate response [3]. Nevertheless, due to the salience of PMDD and almost 20 years of research, the disorder has now been recognized as a distinct diagnostic entity through its inclusion in the newly published DSM-5 [1]. This decision was supported by the work group of experts who examined the literature on PMDD and recommended the appropriate criteria for the disorder in DSM-5 [4]. Pearlstein [5], O'Brien et al. [6] and Epperson et al. [4] suggested that the new category would enhance the legitimacy of the disorder and encourage scientists to find more empirical evidence for PMDD and its treatment. This is essential for public health and reminds us of the urgent need to fill an obvious gap in health care provision.

The diagnosis of PMDD as described in DSM-5 is based on the fulfillment of seven (A to G) criteria. Criterion A refers to the existence of five items in most menstrual cycles and to stage-specificity of the cycle. Criterion B and Criterion C deal with the specific symptoms of the disorder (see Table 1). Criterion D underscores the clinical significance or interference of symptoms with daily-life activities. Criterion E deals with the specificity of PMDD as compared with mood and personality disorders. Criterion F requests the existence of two month's daily prospective ratings. Finally, Criterion G refers to the absence of a medical or drug-induced cause of the disorder.

According to DSM-5 [1], the 12-month prevalence rate of PMDD varies between 1.8% and 5.8% in menstruating women. Although effective treatment for these women is necessary, we first need to develop an appropriate assessment tool based on DSM-5 criteria to assess PMDD. While many prospective and retrospective instruments have been developed to evaluate premenstrual disorders, i.e., Endicott et al.'s [7] Daily Record of Severity of Problems (DRSP), De la Gándara's [8] *Escala de Trastorno Disfórico Premenstrual* (TDP), Steiner et al.'s [9] Premenstrual Symptoms Screening Tool (PSST), and Steiner et al.'s [10,11] Visual Analogue Scale-MOOD (VAS-MOOD), none of these tools addresses all the DSM-5 criteria for assessing PMDD, not even criteria of the

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16

Table 1

Correspondence of CTDP - DSM-5 items with the DSM-5 symptom groups.

DSM-5 criteria	DSM-5 symptoms	CTDP – DSM-5 items
Criterion B	1) Affective lability	7. Sensation of being emotionally much more vulnerable (i.e., attacks of sadness, weeping, or greater
	2) Irritability, anger or increased interpersonal conflicts	sensitivity in the face of rejection) 8. Intense and permanent annoyance 9. Intense and permanent irritation 10. Evident increase of intense and fragment conflict with people
	3) Depressed mood, feelings of hopelessness, or self-deprecating thoughts	frequent conflicts with people 1. Very sad or depressed mood 2. Intense feelings of hopelessness 3. Very intense thoughts of self-disapproval
	 Anxiety, tension, and/or feelings of being keyed up or on edge 	 Marked anxiety Marked tension Sensation of being overloaded or of being close "to the limit"
Criterion C	1) Decreased interest in usual activities	11. Evident loss of interest towards daily life activities (work, school/college) 12. Evident loss of interest in hobbies or leisure activities 13. Evident loss of interest in friends (breaks in social relations)
	 2) Subjective difficulty in concentration 3) Lethargy, easy fatigability, or marked lack of energy 	 14. Considerable difficulty concentrating 15. Acute sleepiness, much greater sensation of being sleepy during the day 16. Much greater sensation of fatigue
	4) Marked change in appetite;overeating; or specific foodcravings5) Hypersomnia or insomnia	 17. Evident lack of energy 18. Very significant changes in appetite; binges or whims regarding specific meals 19. Acute hypersomnia, that is to say, sleeping to excess without apparent cause 20. Insomnia, that is to say, finding it really difficult to sleep, or waking up
	6) A sense of being overwhelmed or out of control 7) Physical symptoms	very frequently during the night 21. Sensation of being overwhelmed or out of control 22. Evident increase in breast size 23. Discomfort in joints or muscles 24. Strong sensation of bloating 25. Clear gain in weight, with difficulty of fitting into clothes, footwear, or wearing rings

previous DSM IV-TR version [2]. The aim of the present study is, therefore, to develop and validate a screening instrument to adequately assess PMDD according to DSM-5.

2. Methods

2.1. Participants and procedure for the item development

The development of the Premenstrual Dysphoric Disorder Questionnaire for DSM-5 (in the original Spanish version: *Cuestionario del Trastorno Disfórico Premenstrual – DSM-5*, hereinafter the CTDP – DSM-5) followed a meticulous procedure in which five experts in clinical assessment and methodology participated. The process involved two phases. regarding the wording of items, as well as the criteria established by Martínez et al. [13] (i.e., representativeness, comprehensibility, and avoiding acquiescence). A dichotomous answer format (Yes/No) was chosen to assess the 25 items in order to comply with the positive/negative approach traditionally used in clinical diagnosis. Furthermore, the instructions urged the respondent to answer *Yes* only if criteria A and D were met. Then, three experts were asked to examine the first version of the tool, and a number of changes were made as a result. Words that were difficult to understand were changed (e.g., 'somnolencia' – 'drows-iness' – instead of '*letargia*' – 'lethargy' – term) or further specified (e.g., next to the word '*hipersomnia*' – 'hypersomnia' – its definition was added).

The preliminary version of the tool, composed of 25 dichotomous items, in its Spanish version, was then administered to a set of students and staff (N = 128) of a state university in Spain. The sample size considered for this data collection fulfilled Nunnally's [14] criterion of being composed at least by 5 participants per item. Participants were part of the target population but not of the sample of the experimental later stage. The women who participated in the preliminary and in the whole study voluntarily answered the assessment tools after their informed consent was obtained (as demanded by the Declaration of Helsinki); almost all women (98%¹) were Spanish. This first study yielded a PMDD prevalence rate of 50%, which was considered too high, given that previous research had reported a frequency of 3–10% [1,2,8,15, 16]. Furthermore, participants' questions, doubts and comments about items and instructions were reported in Spanish in a report-sheet during data collection, and they were qualitatively analyzed later. We, therefore, decided to undertake a second phase in order to refine the CTDP - DSM-5.

In this second phase, two new experts were informed about the outcome of the first phase and invited to analyze the preliminary version of the CTDP - DSM-5 in more detail (taking into account the items, response format, and instructions). Further changes were made following experts' advice. Words emphasizing high distress (i.e., 'very', 'marked', 'intense') were added; items worded as 'experience' were re-worded as 'symptoms'. A final table was also included, where respondents were asked (with instructions) to link the affirmatively responded items to certain situations that would cause disability or interference in daily life (e.g., 'reduced performance at school/college or at work'). The aim of this new section was to ensure the consistency of responses and to avoid social desirability and acceptance bias. This version of the tool was then administered to a small sample of 32 university students. This time, the estimated prevalence of PMDD was about 10%, and the instrument was deemed to have a greater capacity to discriminate between a positive and a negative diagnosis of PMDD. The next step was therefore to subject this version of the CTDP - DSM-5 to empirical validation.

2.2. Participants and procedure for the empirical validation of the instrument

The sample consisted of 2820 women aged between 18 and 60 years (M = 23.43; SD = 7.87) affiliated to the University of the Basque Country.² Women studying/working at the university were invited to voluntarily participate in the study. The CTDP – DSM-5 was administered to students in a classroom setting by previously trained research assistants, after having obtained institutional permission. In the case of

In the first phase, the PMDD symptom set of DSM-5 was used as a reference for creating potential questionnaire items. Based on 11 sets of symptoms, 25 items were derived (see Table 1) and formulated in Spanish. In creating these items we generally retained words and phrases referring to symptoms, although certain changes were made; specifically, we followed Prieto and Delgado's [12] recommendations

¹ Students and staff in this university are mainly Spanish (98% of female undergraduate students, faculty and staff were Spanish in 2015), being the remaining Latin American, European, African, Asian and North American [34].

² The University of the Basque Country is the largest university in the Basque region of Spain. Due to its public status and reputation for high-quality teaching, students from a wide range of socioeconomic backgrounds study at the university. A high percentage of young people in the Basque Country (36.19% of women aged between 18 and 23) enroll in higher education [35].

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