

Validation of Turkish version of Premenstrual Symptoms Impact Survey™ (PMSIS™) for assessing status of premenstrual syndrome in women of reproductive age

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ABSTRACT

Objective: We aimed to evaluate the reliability and validity of a Turkish adaptation of the Premenstrual Symptoms Impact Survey™ (PMSIS™), a six-question health survey that measures the impact of symptoms of premenstrual syndrome (PMS) on an individual's functional health and well-being. **Methods:** The PMSIS™ was independently translated into Turkish and its adaptation to Turkish language was performed via back-translation. The reliability and validity of the PMSIS™ were examined with 63 women of reproductive age, found healthy during annual well-woman gynecologic examination. Premenstrual Syndrome Scale (PMSS), a Turkish questionnaire, was administered to assess the concurrent validity of the PMSIS™. For the assessment of survey data, the content validity, test-retest reliability, Cronbach's alpha, concurrent validity, and construct validity tests were used. **Results:** The content validity index of the Turkish version of PMSIS™ was found as high (91%). After reliability analyses, the intra-class correlation coefficient between the PMSIS™ scores at the first and second assessments was 0.70, showing a good agreement between test and retest values; and the Cronbach's alpha coefficient was 0.89, indicating adequate and high internal consistency. Regarding the concurrent validity, the Pearson's correlation coefficient between the PMSIS™ (first assessment) and PMSS scores was 0.70. Regarding the construct validity, factor analysis revealed that one dimension was found; and factor loading of items ranged from 0.74 to 0.84 and total variant of scale was expressed as 65.1%. The PMSIS™ had a good concurrent and construct validities. **Conclusions:** The Turkish version of PMSIS™ has good reliability and validity properties. It is a reliable, consistent, and valid instrument to assess the status of PMS in women of reproductive age and the outcome of PMS treatment in Turkish population. (*Anatolian Journal of Psychiatry* 2015; 16(3):205-211)

Key words: premenstrual syndrome, Premenstrual Symptoms Impact Survey, reproductive age, woman

Üreme dönemindeki kadınlarda premenstrüel sendrom durumunun değerlendirilmesinde Adet Öncesi Şikayetler Etki Ölçeği Türkçe sürümünün geçerliliği

ÖZET

Amaç: Adet Öncesi Şikayetler Etki Ölçeği (Premenstrual Symptoms Impact Survey™ [PMSIS™]) Türkçe sürümünün geçerlilik ve güvenilirliğinin araştırılması amaçlandı. Bu ölçek, altı soru ile premenstrüel sendromun (PMS), bireyin işlevsel sağlık ve iyilik durumu üzerine etkisini ölçümlenmektedir. **Yöntem:** İngilizce olan PMSIS™'nin Türkçeye bağımsız olarak çevrildikten sonra geri çeviri yöntemi ile adaptasyonu yapıldı. Yıllık sağlıklı kadın jinekolojik muayenesi ile sağlıklı bulunan ve üreme döneminde olan 63 kadın üzerinden ölçeğin geçerliliği ve güvenilirliği

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incelendi. Türkçe bir ölçek olan Premenstrüel Sendrom Ölçeği (PMSÖ), PMSIS™'in eş zamanlı geçerliliğini belirlemek için kullanıldı. Ölçek verilerinin analizinde içerik geçerliliği, test-tekrar test güvenilirliği, Cronbach alfa, eş zamanlı geçerlilik ve yapı geçerliliği testleri uygulandı. **Bulgular:** Ölçeğin içerik geçerliliği yüksek (%91) bulundu. Güvenilirlik analizleri sonucunda, PMSIS™'in birinci ve ikinci uygulamalarının puanları arasında sınıf-içi korelasyon değeri 0.70 bulundu ve ölçeğin test ve tekrar-test sonuçları iyi uyumlu olarak yorumlandı; ayrıca Cronbach alfa değeri 0.89 bulundu ve iç tutarlılığı yeterli ve yüksek olarak yorumlandı. Eş zamanlı geçerlilik analizleri sonucunda, PMSIS™'in birinci uygulaması ve PMSÖ uygulaması puanlarının Pearson korelasyon katsayısı 0.70 bulundu. Yapı geçerliliği analizi için yapılan faktör analizi, özgün ölçekte olduğu gibi tüm maddelerin tek boyutta toplandığını, faktör yüklerinin 0.74-0.84 arasında değiştiğini ve toplam varyansın %65.1 olduğunu gösterdi. PMSIS™ ölçeğinin eş zamanlı ve yapısal geçerlilikleri iyi olarak yorumlandı. **Sonuçlar:** PMSIS™'in Türkçe sürümü, iyi geçerlilik ve güvenilirlik özelliklerine sahiptir. Ölçek güvenilir, tutarlı ve geçerli bir ölçek olarak üreme dönemindeki kadınlarda PMS durumunu ve PMS tedavisinin sonuçlarını Türk toplumunda değerlendirebilir. (*Anadolu Psikiyatri Derg* 2015; 16(3):205-211)

Anahtar sözcükler: Premenstrüel sendrom, Adet Öncesi Şikayetler Etki Ölçeği, üreme dönemi, kadın

INTRODUCTION

A majority of women of reproductive age experience a variety of premenstrual symptoms that can affect their behavior and quality of life and affect family, friends, and working relationships. It is commonly known as premenstrual syndrome (PMS) or more severe PMS, known as premenstrual dysphoric disorder (PMDD). In spite of high prevalence of these common complaints, the exact etiology of PMS is unknown, no theories have been officially proven, and its health burden has been consistently underestimated.¹ Provided there is no organic or underlying psychiatric disease, PMS is defined as a condition that presents with distressing physical, behavioral, and psychological symptoms that regularly recur during the luteal phase of each menstrual cycle and that generally disappear by the end of menstruation. Typically, premenstrual symptoms emerge in early adulthood and increase in the following years. Symptoms of PMS are distinguished from normal physiological premenstrual symptoms because they cause significant impairment to daily activity. Severe PMS is estimated to occur in 15-20% of menstruating women. The prevalence of PMDD, causing the withdrawal from social and professional activities, is 3-8%.²⁻⁵

PMDD was included in Appendix B of Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), 'Criterion sets and axes provided for further study,' aided by the inclusion of specific and rigorous criteria; and there has been an explosion of research on the epidemiology, phenomenology, pathogenesis, and treatment of the disorder.⁶ In 2009, the Mood Disorders Work Group for DSM-5 accepted that the available information on the PMDD has matured sufficiently for it to qualify as a full category in DSM-5. Placing the PMDD in the main text of the DSM-5

will provide greater legitimacy for the PMDD and encourage the growth of evidence-based research, ultimately leading to new treatments.^{6,7}

Several questionnaires determining the status of PMS have been developed in the past two decades. The Premenstrual Symptoms Impact Survey™ (PMSIS™) as a six-question health survey developed to measure the impact of premenstrual symptoms on functional health and well being of women of reproductive age.⁸ PMSIS™ as a short survey can be practical in clinical practice. It is developed for adult women with regular menstrual cycles to evaluate PMS with a recall of the course of last menstrual cycles. As a scientifically valid and brief tool, the PMSIS™ is suitable for assessment of PMS at both the population level and during daily clinical practice when screening for severe premenstrual symptoms need to be required. The purpose of this study is to adapt PMSIS™ for its use in Turkish women to determine the status of PMS and to test its reliability and validation.

METHODS

The PMSIS™ was used with permission from the Optum (Eden Prairie, MN, USA). This study of the adaptation of the Turkish version of PMSIS™ was performed in two phases: Phase I focused on the translation into Turkish, evaluation of content validity and pilot testing. Phase II included the psychometric assessment by analysis of data collected with Turkish version of PMSIS™ to determine its validity and reliability.

Translation

The PMSIS™ was translated using the back-translation technique. In order to test the language equivalence and content validity of the instrument, the original PMSIS™ was independently translated into Turkish by academic staff

from different Turkish universities in a blind manner. The survey translated into Turkish by two bilingual linguistic experts and another expert reviewed the Turkish translations together for inconsistencies with the original English form and minor revisions were performed in some areas. After reviewing both translations of PMSIS™, the most suitable terms were selected and the Turkish version of the PMSIS™ was created. The main rationale for the translation and adaptation was to replace the English items with terms that were linguistically and culturally more appropriate while maintaining sentence lengths similar to those in the original PMSIS™ items. Then the Turkish version of the PMSIS™ was back translated into English by another linguistic expert working as academic staff of Turkish universities. After comparison of the back translated and original forms of the PMSIS™, their meanings were assessed as highly similar. Then, an expert panel of ten faculty members having proficiency in English and Turkish languages was evaluated the translated survey, rating the relevance of each item with a 4-point rating scale changing from 1 (not at all suitable) to 4 (very suitable). These ratings were used for the content validity index (CVI) calculations (9). After obtaining final views of the expert panel and performing final revisions, the authors completed the Turkish version of PMSIS™.

Psychometric assessment

Reliability: We determined the reliability of the Turkish version of PMSIS™ by the help of test-retest and internal consistency methods. Test-retest reliability measures the stability over time by administering the same test to the same subjects with an interval at two points in time. To determine test-retest reliability of the PMSIS™, intra-class correlation coefficients (ICCs) were calculated between the total scores of the first and second measurements in addition to those between the scores on the individual items. The ICC values were evaluated according to the following classification: ≤ 0.4 (poor), 0.40-0.59 (fair to good), 0.60-0.79 (good) and 0.80-1.0 (excellent).¹⁰ The internal consistency of a scale presents its homogeneity. Cronbach's alpha coefficient was used to evaluate the internal consistency of the PMSIS™. An alpha value between 0.70 and 0.90 was accepted as having high meaningful consistency.¹¹ Further, 'alpha if item deleted' and 'item-total correlations' were calculated for each item.

Validity: In addition to the Turkish version of PMSIS™, Premenstrual Syndrome Scale

(PMSS)¹² was administered in order to assess the concurrent validity of the Turkish version of PMSIS™ during the first assessment. To determine concurrent validity, Pearson's correlation coefficient was calculated between the scores of the Turkish version of PMSIS™ (first measurement) and the PMSS. For the determination of construct validity, the factor analysis test was performed.

The sample size for the psychometric evaluation of the Turkish version of PMSIS™ was computed statistically depending on the item number of the survey. In adaptation studies, it is recommended to collect 5-10 times more cases than the number of items in the questionnaire.^{13,14} Given that PMSIS™ has six items, sample size for the validation and reliability of the instrument was determined as more than 60 women. Among the women of reproductive age who were found healthy during annual well-woman gynecologic examination in our gynecologic outpatient service, totally 69 eligible women were invited, six subjects did not agree to participate in the study. The test-retest reliability was examined using a 14 day interval with 63 qualified and eligible women of reproductive age with a mean age of 27.7 ± 6.3 years, with a range of 22-47 years. The exclusion criteria were pregnancy, having irregular menstrual cycles, history of polycystic ovarian disease, use of hormonal contraceptive methods or taking any hormonal treatment, history of surgery related internal genital organs, and unwillingness to continue to fill the forms of study. Verbal consent to participate in the study was obtained from all the subjects. They took part in the study voluntarily and without receiving economical compensation.

The PMSIS™

It is a self-administered survey that consists of 6 items: PMSIS item 1, felt frustrated because of symptoms; PMSIS™ item 2, mood swings because of symptoms; PMSIS™ item 3, symptoms limited ability to concentrate; PMSIS™ item 4, got tense because of symptoms; PMSIS™ item 5, symptoms left you too tired to work; and PMSIS™ item 6, symptoms kept you from socializing. Since all selected items for the PMSIS™ scale in the same direction and share a common metric, total score was calculated by simply summing across all six items. Each re-sponse had an impact severity range of 1 (no impact) to 5 (high impact). The scale is formed by simple summation of the items and transformed to a 0 (no impact) to 100 (highest impact) range to simplify interpretation. Higher scores obtained

from the PMSIS™ indicate higher severity of complaints.⁸

The PMSS

The PMSS was developed by Gencdogan¹² as a new scale for the assessment of PMS. In this study, this scale was selected because of its good psychometrical properties as a Turkish questionnaire. The PMSS has 44 items scored as a 5-point Likert scale. Each item is filled in the PMSS form was marked by taking notice of 'having this condition the week before menstruation.' The PMSS items are scored similar to the PMSIS™. There are 9 subscales on the PMSS. These are depressive feelings (items 1-7), anxiety (items 8-11, 13, 15, 16), fatigue (items 12, 14, 17, 18, 25, 37), irritability (items 19-23), depressive thinking (items 24, 26-30, 44) pain (items 31-33), changed appetite (items 34-36), changed sleep (items 38-40) and swelling (items 41-43) subscales. The existence of PMS is determined according to subscale scores and the total PMSS score in the original study. The total PMSS score is the sum of the subscale scores. The lowest possible PMSS total score is 44 points and the highest is 220. The instrument developers suggested that girls who had a total PMSS score of 111 or higher could be accepted as having PMS. Higher scores obtained from the PMSS™ indicate more severe complaints.

Statistical analysis

Descriptive statistics were calculated as mean±SD or median (min-max) values for the age, duration of menstrual cycle, and gravidity of patients and scores of surveys. Only complete questionnaires were included in the analyses. A p value of less than 0.05 was considered as significant.

RESULTS

All the study participants completed the PMSIS™ and PMSS questionnaires. Most of the participants (n=37) had graduated from the university and the rest (n=26) had graduated from the high school. They had a median duration of menstrual cycle of 29 (26-35) days and a median gravidity of 1 (0-3). The CVI of the Turkish version of the PMSIS™ was 91%. The mean score of PMSIS™ at the test and retest measurements were 43.3±20.8, with a range of 0-75, and 40.3±21.3, with a range between 0-87.5, respectively. The mean score of PMSS was 104.6±31.3, with a range of 44-167.

Reliability

Table 1 shows item distribution of the PMSIS™ test and retest data. Overall answering quality of the Turkish version of PMSIS™ was good. No systematic rejection was seen for any items in the PMSIS™ test. The ICC coefficient between the PMSIS™ scores at the first and second assessments was 0.70 (95% CI: 0.58-0.81; confidence interval determined by empirical bootstrap), showing a good agreement between test and retest scores.

Table 1. Item response distribution of PMSIS™ test and retest data

Item no.	Time	Response distribution				
		1	2	3	4	5
1	Test	15	9	22	12	5
	Retest	16	16	17	12	2
2	Test	6	6	26	20	5
	Retest	6	16	22	17	2
3	Test	12	16	27	8	0
	Retest	15	18	21	9	0
4	Test	5	14	20	20	4
	Retest	5	15	21	18	4
5	Test	13	17	25	8	0
	Retest	11	17	21	13	1
6	Test	9	25	20	9	0
	Retest	14	23	21	5	0

The Cronbach's alpha coefficient was found as 0.89, indicating good internal consistency. The item-total correlations of PMSIS™ test data ranged from 0.629 and 0.765 (p=0.01) (Table 2). The inter-item correlations of PMSIS™ test data changed from 0.49 to 0.79 (p=0.01) (Table 3). Overall, after reliability tests, the reliability of items of PMSIS™ was accepted as good.

Validity

Regarding concurrent validity, the Pearson's correlation coefficient between the PMSIS™ (first assessment) and PMSS scores was 0.70 (p=0.032), and this strong positive correlation revealed that there was a meaningful agreement between the scores of these questionnaires, indicating the concurrent validity of Turkish version of PMSIS™. Related to the construct validity, firstly, Kaiser-Meyer-Olkin (KMO) value was found as 0.857 and Bartlett's test for sphericity was found as statistically significant, (p=0.001), indicating the dataset was appropriate for a factor analysis. The sample was

Table 2. Item-total correlations of PMSIS™ test data

PMSIS™ item no	Corrected item-Total correlation	Cronbach's alpha if item deleted
Item 1	0.730	0.870
Item 2	0.701	0.872
Item 3	0.629	0.882
Item 4	0.765	0.861
Item 5	0.729	0.868
Item 6	0.717	0.870

Table 3. Inter-item correlations of PMSIS™ test data

Item no	1	2	3	4	5	6
Item 1	1.000	0.659	0.551	0.696	0.531	0.508
Item 2		1.000	0.490	0.629	0.539	0.515
Item 3			1.000	0.514	0.534	0.517
Item 4				1.000	0.603	0.619
Item 5					1.000	0.791
Item 6						1.000

considered adequate if KMO value was more than 0.60, and if Bartlett's test was significant (p-value less than 0.05). Secondly, factor analysis was performed and one dimension was found, and factor loading of items ranged from 0.74 to 0.84 and total variant of scale was expressed as 65.1%. These findings indicated that all items were nicely fit on each component and the Turkish version of PMSIS™ had a good construct.

DISCUSSION

We completed this study with 63 subjects. Overall, the Turkish version of PMSIS™ provided good reliability and validity for the evaluation of women with PMS. All the six items of the survey reflected the status of PMS in good agreement. The PMSIS™ and PMSS scores provided a meaningful agreement during the measurement of status of PMS, indicating the potential of PMSIS™ to successfully evaluate the impact of PMS on the functional health and well-being of women of reproductive age. The Turkish version of PMSIS™ might be considered

as a valid and reliable scale to evaluate the status of PMS.

After the introduction of the Menstrual Distress Questionnaire in 1968¹⁵ to evaluate the severity of premenstrual symptoms, various tools have been developed in women with premenstrual disorders in a retrospective or prospective fashion. To reach to an accurate diagnosis, the regularity of the symptoms in accordance with the cycle is most accurately determined by prospective daily documentation during at least two menstrual cycles because of the possible interpersonal variability in symptoms between menstrual cycles.¹ Matsumoto et al.¹ concluded that the prospective recording was not always carried out in clinical practice. A retrospective symptom record, however, depends on the memory of women and it is difficult to collect information related to many types of complaints and their severity. In the current literature, there were several studies performed with different questionnaires related to PMS; overall, they provided inconsistent results in defining the affected population. Assumptions related to those definitions may contribute to the evaluation of the impact of their burden on health.¹⁶ Wallenstein et al.⁸ developed the PMSIS™ to identify the health-related quality of life domains¹⁷ those were influenced mostly by premenstrual symptoms. In their study, 68 questions were administered to 971 women aged 18-45 years using a web-based format. Six items were used for entry criteria. They found that 6% of the women were at risk for PMDD and 17.3% of them were at risk for clinically significant PMS. They demonstrated that the PMSIS™ could differentiate the patients with or without PMS/PMDD. They stated that individuals might use the instrument to evaluate the impact of their premenstrual symptoms on daily functioning and quality of life and receive norm-based feedback that could then be shared with their medical provider. They also noted that public health researchers might find the tool useful for assessing the degree to which premenstrual symptoms that were below standard diagnostic criteria create health-related quality of life or economic burden to the women of reproductive age. Halbreich et al.¹⁸ extensively reviewed the prevalence, impairment, impact, and burden of PMS/PMDD. They suggested that appropriate recognition of the disorder could lead to management of more women suffering from PMS/PMDD. In the study by Gencdogan¹² the status of PMS was assessed in university students with a Turkish self-administered question-

naire including 44 items developed to evaluate the status of PMS. They validated the PMSS with the Turkish version¹⁹ of Premenstrual Assessment Form developed by Halbreich et al. in 1982.²⁰ They noted that the PMSS had reliability and validity for the evaluation of premenstrual symptoms. Erbil et al.²¹ conducted a study to assess premenstrual complaints in Turkish university students. They used the PMSS developed by Gencdogan.¹² They found that nearly half of the girls had PMS. The Turkish version of PMSIS™ provided considerable accordance with the results of PMSS in our study settings and had important advantage because of its small number of items. In a study by Yang et al.,²² PMSIS™ was used to measure impact of premenstrual disorders on the health-related quality of life and sexual drive. The authors concluded that in accordance the higher scores of PMSIS™, the negative impact of premenstrual disorders increased on health-related quality of life and sexual function. The results of this study also supported the possible benefits of contribution of instruments to measure the impact of premenstrual disorders on evaluation of overall quality of life.

The current research has some limitations. The subjects of the study was enrolled from only one

of the hospitals in the city in which authors have worked. They may not correspond to the entire population. Another potential limitation of this study is the use the PMSIS™ with six items and the PMSS with 44 items in the same settings to assess PMS status since there is no brief and validated questionnaire in Turkish language. Despite these limitations, with the contribution of appropriate selection of eligible women after well-woman gynecologic examination with appropriate inclusion criteria to choose women with natural ovulatory cycles, the Turkish version of PMSIS™ provided the criteria of a useful instrument to assess PMS.

In conclusion, the Turkish version of PMSIS™ can be used as a reliable, consistent, and valid instrument in assessing the status of premenstrual disorders in the Turkish population. The length of the questionnaire may be a limitation to use especially in clinical settings because if the premenstrual symptoms are one of many aspects of patient-reported outcomes being assessed since a long questionnaire may be burdensome to patients. The Turkish version of PMSIS™ as a short and practical instrument need to be used in further studies for the evaluation of PMS in research and clinical settings.

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