

The Turkish Adaptation, Validity, and Reliability of the Internal States Scale

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ABSTRACT

Introduction: The Internal State Scale (ISS) was developed to simultaneously assess manic and depressive symptoms in bipolar disorder. In the present study, the validity and reliability of the Turkish version of ISS (ISS-TR) were examined. The present study aimed to present the psychometric properties of this scale.

Methods: The sample consisted of 200 outpatients with bipolar disorder and 49 healthy controls. Participants completed the Turkish Internal State Scale (ISS-TR), the Brief Psychiatric Rating Scale (BPRS), the Hamilton Depression Rating Scale (HDRS), and the Young Mania Rating Scale (YMRS).

Results: Reliability analyses revealed that the Cronbach alfa coefficient of ISS was 0.88 for the whole sample. Item-total correlations ranged from 0.15 to 0.78. Two factors emerged as a result of factor analysis: "mania" and "depression-well-being." Test-retest correlations were determined for the mania subscale as $r=0.654$, $p<0.01$ and for the

depression-well-being subscale as $r=0.356$, $p<0.01$. The correlations between BPRS and both subscales were quite high. The correlation between HDRS and the depression-well-being subscale was higher ($r=0.475$) than that between HDRS and the mania subscale, whereas the correlation between YMRS and the mania subscale was higher ($r=0.818$) than that between YMRS and the depression-well-being subscale. It was seen that ISS could discriminate between the clinical and healthy control samples. In addition, it was observed that the mania subscale predicted a manic period more strongly, while the depression-well-being subscale predicted a depressive period better.

Conclusion: ISS is a valid and reliable scale that can be used to simultaneously assess manic and depressive symptoms. It is thought that ISS will be useful in the recognition of prodromal symptoms and in the process of maintenance treatment.

Keywords: Bipolar disorder, manic, depressive, self-report

INTRODUCTION

The lifetime prevalence of bipolar disorder (BB) varies between 0.5% and 1.5% (1,2). It is chronic and has multiple and successive major depressive and (hypo)manic episodes (3). The disorder mostly begins with a depressive episode. The severity and frequency of episodes increase over time, and every relapse causes a decrease in the amount of stress required for the occurrence of a new episode (4). Longitudinal studies have revealed that subsyndromal hypomanic and depressive symptoms continue their existence even in remission (5,6).

Bauer et al. (7) noticed that there was no self-reporting scale for manic symptoms, although there were many scales for depressive symptoms. Therefore, they developed the Internal States Scale (ISS). They tried to create an easily understandable inventory about mood states using observation-based scales that investigated manic and depressive episodes. The chosen items included four main symptom groups, namely activation level, well-being or euphoria, depression, and irritability or low concentration, which could be observed in both mood states (7). They stated that the scale could be useful in searching for rapid-cycling BB, cyclothymia, seasonal mood disorder, and manic and/or mixed states triggered by antidepressants because it was able to evaluate both manic and depressive symptoms simultaneously. ISS is composed of 15 items, while four subscales emerged as a result of factor analyses: activation, depression index, perceived conflict, and well-being. The items are about how a person perceives his/her symptoms instead of questioning his/her behavioral patterns (e.g., sleep routine). Three subscales predicting symptom severity are separated in terms of symptoms: the "activation" subscale for manic symptoms, the "depression index" for depressive symptoms, and "perceived conflict" for general psychopathology. ISS examines mood symptoms in the last 24 hours. The activation subscale and depression index subscale were found to be highly correlated with the Young Mania Rating Scale (YMRS) ($r=0.60$) and the Hamilton Depression Rating Scale (HDRS) ($r=0.84$), respectively. The perceived conflict subscale was found to be related to clinician-rated measures about the general psychopathology [the Brief Psychiatric Rating Scale (BPRS) (8)]. In addition, they pointed out that the well-being and activation subscales could be used to discriminate between mood episodes (depressive-manic/hypomanic-subsyndromal/euthymic) (7,9,10).

ISS has been used in many different researches: efficiency of cognitive-behavioral therapy (11,12,13,14), functioning and quality of life in BB (15,16,17,18,19), and others. In addition, different researchers have used ISS to look at current mood symptoms during their research (20,21,22,23,24,25,26,27,28).



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Patients are able to recognize their mood symptoms earliest and explicitly in BB. Recurrent episodes and subsyndromal symptoms in-between episodes are generally experienced. If self-reporting scales like ISS were to be used more widespread in daily clinical practice, then early intervention and overcoming subsyndromal symptoms effectively could be possible. Thus, it is expected that difficulties experienced by clinicians in monitoring patients can be decreased and the quality of life of bipolar patients may be enhanced. The aim of this research is to introduce ISS, which can be useful in clinical practice and research, to Turkish mental health professionals and bipolar patients.

METHODS

Participants

Two hundred outpatients diagnosed with BB and 49 healthy controls participated in the study. The clinical sample was recruited from the Mood Disorders Clinic of the Psychiatry Department at Uludağ University in Bursa, Turkey, and the Mood Disorders Clinic of Psychiatry Department at Celal Bayar University in Manisa, Turkey. The patients were diagnosed with "Bipolar I Disorder" (BB-I) and "Bipolar II Disorder" (BB-II) by psychiatrists according to semi-structured clinical interview for the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (29) and they met the criteria for participation.

The control group was recruited from healthcare personnel and students of Uludağ University Medical Faculty who had no past or current psychiatric problems.

Measures

Internal States Scale (ISS): ISS is a self-reporting instrument for manic and depressive symptoms within the last 24 hours. This 15-item scale consists of four subscales with high internal consistency: activation (ISS-activation), depression (ISS-depression index), perceived conflict (ISS-perceived conflict), and well-being (ISS-well-being). When the activation and well-being subscales of ISS are evaluated together, they can discriminate between mood states. According to the algorithm, having a score greater than 155 from the activation subscale in conjunction with a score greater than 125 from the well-being subscale indicates (hypo) mania; whereas, having a score greater than 155 from the activation subscale together with a score less than 125 from the well-being subscale indicates a mixed state. For euthymia, a person needs to score less than 155 from the activation subscale and score greater than 125 from the well-being subscale. When a participant scores less than 155 from the activation subscale and less than 125 from the well-being subscale, this indicates a depressive mood.

BPRS: The scale was developed by Overall and Gorham (8) to examine psychotic and depressive symptoms and their severity in schizophrenia and other psychotic disorders. It is composed of 18 items and each item is rated between 0–6. Gulgun Yanbastı prepared the Turkish version.

HDRS: HDRS was structured as an interview by Williams in 1978 (30). The scale is composed of 17 items. The presence of a symptom and its level of severity are determined by the clinician. The score interval of the scale is 0–53. Higher scores indicate an increase in the severity of depression. The Turkish validity and reliability study was made by Akdemir et al. (31). The Cronbach alpha was found to be 0.75, while the test–retest reliability was measured as 0.85.

YMRS: This 11-item scale was developed by Young et al. (32) in 1978. Every item is rated on a 0–4 scale. The rating of severity is based on both the patient's declaration about their subjective state during the last 48 hours and the clinician's impressions about the patient during the session. The Turkish validity and reliability study was made by Karadağ et al. (33), and the internal consistency coefficient was found to be 0.79.

Procedure

Prestudy

Permission was obtained from Dr. Mark Bauer. The research was approved by the Uludağ University Ethics Committee (2013-3/12). ISS was translated to Turkish by three clinicians from psychiatry and psychology areas. This first version of the scale was applied to 20 psychology undergraduates and this version was seen to be comprehensible. Back-translations were done by a psychiatrist with a specialist degree in medicine and a professional translator. This draft was sent to Dr. Bauer. While finalizing the Turkish scale, the feedbacks and suggestions of Dr. Bauer were taken into consideration. After minor revisions, it was decided that the Turkish translation of ISS corresponded to the original scale.

Data Collection

Before the application, participants were given information about the aims and procedure of the research to ask for their informed consent. All participants in both the clinical and control groups were evaluated by a psychiatrist with a semi-structured interview based on DSM-IV. During this interview, ISS, HDRS, and YMRS were given and their socio-demographic characteristics were recorded.

To evaluate the test–retest reliability, ISS was readministered at least two weeks after the first application of the scale to 34 patients who were already euthymic in the first session. The criteria for euthymia were: HDRS score <7 and YMRS score <5.

Statistical Analysis

To examine reliability of the scale, the internal consistency Cronbach alpha coefficient and the item-total correlation coefficient were used. Also, the Pearson correlation method and repeated measured t-tests were applied for the test–retest reliability. To evaluate validity, the correlations between ISS-TR and other psychiatric rating scales (BPRS, HDRS, and YMRS) were examined with the Pearson correlation method. The principal components method was used for the construct validity. Only the factors with an eigenvalue greater than 1 and only the items with a factor load greater than 0.4 were analyzed. For the analysis of the discriminant validity of ISS-TR, a multivariate analysis of covariance (MANCOVA) was conducted to compare ISS-TR scores of the clinical and control groups while controlling for age and educational level as covariants. To examine to what extent Factor 1 and Factor 2 predicted manic and depressive symptoms, a regression analysis was carried out. Also, discriminant analysis was used to evaluate to what extent the factors could predict mood episodes.

RESULTS

Sample Characteristics

The sample comprised 200 patients with BB (80.3%) and 49 healthy controls. The mean of age of the clinical group was found to be 42.98 ± 26.93 years, while of the control group was found to be 31.71 ± 10.84 years ($t=2.87$, $p<0.05$). In the clinical group, there were 114 women (57%), while in the control group, there were 30 women (61.2%). In terms of the educational level, the distributions of the clinical and control groups were as follows: illiterate 1% ($n=2$) and 0%, literate 1% ($n=2$) and 2%

(n=1), primary school graduate 19.5% (n=39) and 0%, secondary school graduate 8% (n=16) and 0%, high school graduate 24% (n=48) and 22.5% (n=11), and college graduate 46.5% (n=93) and 75.5% (n=37), respectively ($p<0.05$). Regarding current mood episodes, it was seen that 24 participants (9.6%) were on a major depressive episode, 41 participants (16.5%) were on a manic episode, and 135 participants (54.2%) were in remission. The average duration of illness was found to be 14.26 ± 9.12 , while the average number of episodes was 7.70 ± 7.27 .

The Scores of the Scales

The scores of BPRS, HDRS, and YMRS of the clinical and control groups are shown in Table 1. In addition, the Cronbach alpha coefficient of HDRS was found to be 0.927 and the item-total correlations were 0.382–0.827. For YMRS, the Cronbach alpha coefficient was calculated as 0.943 and the item-total correlations were between 0.568 and 0.905.

Validity and Reliability of the Findings

Internal consistency

The Cronbach alpha coefficient of ISS-TR was found to be 0.88. Item-total correlations were between 0.15 and 0.78. It was seen that the item-total correlation of the seventh item of the scale was low (Table 2).

Test–retest reliability

The test–retest correlation of Factor 1 was found to be $r=0.654$, $p<0.01$, whereas the test–retest correlation of Factor 2 was calculated as $r=0.356$, $p<0.05$. The test–retest values of the two factors were also examined with related measures t-test. It was found that the means of the related measures of these two factors were not differentiated (for the mania subscale: $t(33)=0.417$, $p>0.05$; for the depression subscale: $t(33)=-1.51$, $p>0.05$).

Construct validity

As a result of principal components analysis, two factors emerged (Table 3).

In this new factor structure, it was observed that the items of Factor 1 were related to mania, while the items of Factor 2 were related to both a depressive episode and well-being. Therefore, Factor 1 was entitled as the mania subscale and Factor 2 as the depression-well-being subscale. The analyses were carried out in terms of these two factors (Table 4).

Convergent validity

The correlation between BPRS and the mania subscale was found to be $r=0.602$ ($p<0.01$), while its correlation with the depression-well-being

subscale was 0.670 ($p<0.01$). The correlation between HDRS and the mania subscale was calculated as $r=0.026$ ($p>0.01$), while its correlation with the depression-well-being subscale was $r=0.475$ ($p<0.01$). The correlation between YMRS and the mania subscale was found to be $r=0.818$ ($p<0.01$), while its correlation with the depression-well-being subscale was $r=0.368$ ($p<0.01$).

As a result of using regression analysis for examining to what extent the mania subscale predicted manic symptoms, it was shown that this subscale could predict manic symptoms: $R=0.82$; $R^2=0.67$, $F(1.245)=496.48$; $p<0.0005$. The regression analysis for examining to what extent the depression-well-being subscale predicted depressive symptoms revealed that this factor could also predict depressive symptoms: $R=0.475$; $R^2=0.225$, $F(1.247)=71.89$, $p<0.0005$. Since this factor was bipolar, to what extent it could predict manic symptoms was also examined ($R=0.368$, $R^2=0.136$, $F(1.247)=38.74$, $p<0.001$). This finding showed that this factor could predict depressive symptoms better than manic symptoms.

Discriminant validity

To examine whether ISS-TR could discriminate between the clinical and healthy control groups, MANCOVA was performed while controlling for the age and educational level. It was seen that the difference between the two groups was statistically significant and ISS-TR could discriminate between the two groups (Table 5).

The discriminant analysis was applied to examine to what extent the mania and depression-well-being subscales could predict mood episodes. A total of 247 cases were analyzed. Univariate ANOVA revealed that mood episodes differed significantly on each of the two factors (for mania: $F=214.45$, $df=3.243$, $p<0.001$; for depression-well-being: $F=68.19$, $df=3.243$, $p<0.001$). Separate discriminant functions were defined for the mania and depression-well-being subscales, and it was then seen that

Table 2. Mean, standard deviation, item-total correlations, and alpha values after removing outliers

Item	Mean	SD	Item-Total Correlation	α
ISS-TR-1	22.63	28.78	0.782	0.863
ISS-TR-2	17.73	26.30	0.696	0.868
ISS-TR-3	45.71	27.52	0.321	0.883
ISS-TR-4	12.83	24.84	0.728	0.867
ISS-TR-5	41.74	26.35	0.369	0.881
ISS-TR-6	14.29	23.36	0.698	0.869
ISS-TR-7	15.34	26.48	0.147	0.889
ISS-TR-8	16.23	28.55	0.784	0.863
ISS-TR-9	13.52	26.07	0.245	0.885
ISS-TR-10	13.97	26.54	0.788	0.864
ISS-TR-11	13.28	24.76	0.555	0.873
ISS-TR-12	13.97	27.21	0.775	0.864
ISS-TR-13	18.74	42.47	0.297	0.893
ISS-TR-14	11.26	22.49	0.699	0.869
ISS-TR-15	36.32	28.52	0.501	0.876
ISS-TR-16	49.01	20.24	0.360	0.880

ISS: Internal State Scale; SD: standard deviation.

Table 1. Mean and standard deviation values of the scales

		n	Mean	SD
BPRS	Clinical Group	200	8.68	9.19
	Control Group	49	4.47	4.87
HDRS	Clinical Group	200	4.17	6.57
	Control Group	49	1.49	1.95
YMRS	Clinical Group	200	5.73	10.19
	Control Group	49	1.08	2.15

BPRS: Brief Psychiatric Rating Scale; HDRS: Hamilton Depression Rating Scale; YMRS: Young Mania Rating Scale; SD: standard deviation.

Table 3. Results of factor analysis of the Turkish version of the Internal States Scale

Item No	Factor 1	Factor 2
ISS-TR-1	0.791	0.274
ISS-TR-2	0.697	0.459
ISS-TR-3	0.499	-0.628
ISS-TR-4	0.780	0.218
ISS-TR-5	0.548	-0.640
ISS-TR-6	0.764	0.190
ISS-TR-7	0.051	0.864
ISS-TR-8	0.876	-0.124
ISS-TR-9	0.154	0.857
ISS-TR-10	0.883	-0.134
ISS-TR-11	0.507	0.588
ISS-TR-12	0.876	-0.143
ISS-TR-13	0.252	0.646
ISS-TR-14	0.748	0.232
ISS-TR-15	0.667	-0.506

Table 4. Factor structure of the Turkish version of the Internal States Scale

Factor 1	Item
ISS-TR-1	Today, my mood is changeable
ISS-TR-2	Today, I feel irritable
ISS-TR-4	Today, I feel like people are out to get me
ISS-TR-6	Today, I feel impulsive
ISS-TR-8	Today, my thoughts are going fast
ISS-TR-10	Today, I feel overactive
ISS-TR-12	Today, I feel "sped up" inside
ISS-TR-14	Today, I feel argumentative
ISS-TR-15	Today, I feel energized
Factor 2	Item
ISS-TR-3	Today, I feel like a capable person
ISS-TR-5	Today, I actually feel great inside
ISS-TR-7	Today, I feel depressed
ISS-TR-9	Today, it seems like nothing will ever work out for me
ISS-TR-11	Today, I feel as if the world is against me
ISS-TR-13	Today, I feel restless

the values differed between mood episodes (respectively, $\chi^2(6)=427.57$, $p<0.0005$; $\chi^2(2)=112.22$, $p<0.0005$). The correlations between the predictor variables and discriminant functions suggested that the mania subscale could predict manic episode better than the depression-well-being subscale, while the latter predicted depressive episodes better than the mania subscale. It was seen that the current factor structure had difficulty in discriminating between healthy controls from participants in remission, whereby 59.2 % of healthy controls were predicted as remission. Overall, the discriminant function successfully predicted the outcome in 65.6% of cases (with accurate predictions being made for 75% of the patients in a depressive episode, for 85.4% of the participants in a manic episode, for 69.9% of patients in remission, and for 32.7% of the healthy controls).

Table 5. Results of MANCOVA (covariants: age and educational level)

		Mean	SD	F	Significance
Mania	Clinical healthy control	176.17 96.14	13.45 27.66	6.58	0.011
Depression-well-being	Clinical healthy control	158.38 104.73	6.86 14.11	11.78	0.001

SD: standard deviation

DISCUSSION

In this study, it was seen that the Turkish form of ISS was able to assess manic and depressive symptoms among BB patients and was sufficiently reliable and valid, like the original scale.

From reliability analyses, the Cronbach alpha coefficient was found to be 0.88. Because the internal consistency value is statistically desired to be greater than 0.80, this value indicated that the internal consistency of ISS-TR was sufficient (34). In all groups, the item-total correlations varied between 0.15 and 0.78. Only the item-total correlation of the seventh item of the scale "Today, I feel depressed" was lower than the item-total correlations of the other items. The results of factor analysis revealed that no statistical problems occurred, in spite of its low correlation. This low item-total correlation of the item might be related to subsyndromal depressive symptoms among patients in remission and the "affective lability" among manic patients; however, it may also be associated with the fact that the word "depression" does not sufficiently reflect a depressive mood in the Turkish language. With regard to test-retest reliability, ISS-TR was consistent over time (for the mania subscale: $r=0.654$, $p<0.01$; for the depression-well-being subscale: $r=0.356$, $p<0.05$). Although the scores of both subscales were statistically significant, it was seen that the test-retest correlation of depression-well-being was relatively low. When this was examined with item analysis, the third and fifth items regarding well-being were found to be inconsistent over time. This finding might be related to the fact that some of the participants experienced frequent mood swings.

Regarding the construct validity of ISS-TR, a two-factor structure emerged. This structure explained 68.4% of the total variance. It was seen that the mania subscale was composed of the activation and the perceived conflict subscales of the original scale. While the depression-well-being subscale was comprised of particularly the depression index and the well-being subscales and also one item each of perceived conflict and activation subscales. When the items of each factor were examined, it was remarked that the mania subscale was more associated with manic symptoms. On the other hand, as evident from its name, the depression-well-being subscale had a bipolar structure. Although four items of this subscale were related with depressive symptoms, the last two were about well-being. The possible reasons for this finding might be that, as was shown in the discriminant analysis, the healthy control group was not sufficiently different from the other groups. Although it could be discriminated from depressive group, it was not entitled to be a separate dimension and instead stayed at the same dimension. This might be linked to the fact that participants in the healthy control and/or remission groups misunderstood some of the items about depression and gave high scores to those items. In this regard, participants of those groups got supra-threshold scores from

HDRS (5,6). So, this subscale could discriminate a depressive episode; however, it could not discriminate the ones in remission or the healthy controls, since they obtained depression scores.

Another remarkable point regarding the depression-well-being subscale is that items of well-being (Item 3 and Item 5) had negative loads. This might be interpreted as indicative of depression. It came to mind that these items might be reversely scored. However, this scoring was not made on the original scale, thus reverse scoring of these items was also not applied in the current research.

Another point of discussion was that "Today, I feel energized" (Item 12) fell into the mania subscale, whereas "Today, I actually feel great inside" (Item 5) was in the depression-well-being subscale. Since mania and depression represent opposite symptoms, in the scales including both dimensions it is normal that some of the same items are placed with high factor loads in mania and depression factors separately (i.e., they have a positive load in one factor and vice versa.). In our study, a similar finding was obtained. Generally, a factor load of 0.4 and higher is accepted. Among items with factor loads higher than 0.4 in more than one factor, items are included in the factor with the highest factor load. In our research, item 15 was represented in the mania subscale because its positive load was higher on that scale, while item 5 was represented in the depression-well-being subscale with a higher negative load.

Regarding convergent validity of ISS-TR, a modestly high correlation between BPRS and the two subscales of ISS-TR showed that the Turkish form was sufficient to examine general psychopathology (7). Its correlations with HDRS revealed that there was a statistically significant correlation between HDRS and the depression-well-being subscale ($r=0.475$, $p<0.01$). The significant correlation between YMRS and the mania subscale ($r=0.818$, $p<0.01$) represented this factor as being linked with manic symptoms. Regression analyses pointed out that the mania subscale could predict manic symptoms, while the depression-well-being subscale was able to predict both manic and depressive symptoms.

The analyses of discriminative validity revealed that ISS-TR could discriminate between clinical and healthy control groups. Also, it was seen that factors were differentiated into mood episodes, where the mania subscale could predict manic episodes better than the other subscale, whereas the depression-well-being subscale could predict depressive episodes better than the mania subscale. These findings are partly similar to Bauer et al. (7,9) and Glick et al. (10).

On the whole, two factors of ISS-TR could predict manic and depressive symptoms at a sufficient level and they could discriminate between manic and depressive episodes. It was seen that the Turkish ISS had a different factor structure from the original four-factor ISS (activation-perceived conflict-well-being-depression index). In the Turkish form, items of these factors were distributed between two factors. In the original study, the activation subscale was stated as a better predictor of manic symptoms. In the present study, this role was played by the mania subscale. Similarly, the high correlation between the depression index subscale and depressive symptoms was observed in the depression-well-being subscale of the Turkish scale.

Bauer et al. (7) deduced that the main characteristic of mania was activation. Their deduction was based on the high correlation between the activation subscale of ISS and YMRS, this subscale being able to discriminate patients with manic symptoms from healthy controls, also hypomanic and manic patients scored higher with this subscale. Even though a dissimilar factor structure was observed in the present study, considering the high correlation between the mania subscale and YMRS, the correlations of the items of this subscale with YMRS were examined. High correlations were found in the items especially related to activation (Item 8, Item 10, Item 12) (respectively, $r= 0.817$; 0.804 ; 0.837 , $p<0.05$). Thus it might be said that the findings of this research were in line with the implications of the original study. Also DSM 5 made activation as the main criterion for mania and emphasized the need to consider this symptom for predicting mania (35). In addition, the activation concept has recently been examined in the research about cognitive styles in BB. These studies showed that extreme positive or negative appraisals of symptoms related to activation led to mood swings (24).

Since subscales of ISS-TR did not possess a homogenous structure, cut-off scores of the subscales were not measured. In this respect, it is impossible to discriminate mood episodes in scores, like in the original study. However it was seen that several researchers used subscales of ISS for their analyses (23,36,37). Therefore, Turkish researchers may benefit from two subscales of ISS-TR whose associations with manic and depressive symptoms were shown in their prospective studies. Also, discussing the items of the scale with the patient during the treatment process may be elaborated on in the sessions.

Since ISS enables patients to make a self-evaluation about the process of illness, it may be helpful in long-term monitoring of the disorder. Also, as Bauer et al. stated, it may be used in monitoring rapid-cycling BB (7). Many studies point out that subsyndromal symptoms have a negative effect on functioning (37,38). It is thought that clinicians may benefit from ISS in the recognition, monitoring, and treatment of subsyndromal symptoms.

The most important limitation of this research is the difference between the healthy control group and clinical group with regards to age and education level. However we tried to control this difference statistically by using MANCOVA.

As a valid and reliable scale, ISS may be used among patients primarily with mood disorders (especially BB) and analog samples comprising university undergraduates, as well as in other medical disorders (like dermatological disorders) in which bipolar symptoms might be observed. This scale may be helpful for both clinicians and researchers to evaluate and to monitor illness severity in daily clinical practice and clinical research.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Uludağ University School of Medicine.

Informed Consent: Written informed consent was obtained from participants who participated in this study.

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