INDEPENDENT VALIDATION OF PARKINSON'S DISEASE SLEEP SCALE 2ND VERSION (PDSS-2)

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Abbreviations: **ESS**= Epworth Sleepiness Scale; **HYS**= Hoehn-Yahr Scale; **MDS-UPDRS**=The Movement Disorder Society-sponsored Unified Parkinson's Disease Rating Scale; **NMS**= non-motor symptoms; NPV = Negative Predicting Value; **PD**= Parkinson's disease; **PDSS-2**= Parkinson's Disease Sleep Scale 2nd version; **PGI**= Patient's Global Impression; PPV = Positive Predicting Value;

ABSTRACT

Sleep problems are one of the most common non-motor symptoms of Parkinson's disease (PD). The Parkinson's disease Sleep Scale 2nd version (PDSS-2) was published in 2011 showing satisfactory clinimetric results. We performed an independent testing of the scale adding further information on its clinimetric properties.

In this nationwide study 537 PD patients were enrolled. Besides PDSS-2, we assessed Patient's Global Impression-Severity (PGI) scale on sleep disturbances, Non-motor Symptoms Scale and MDS-UPDRS. Following the Classical Theory of Tests we performed descriptive data analysis, factor analysis, reliability, validity and precision measurements. Subsequently, we evaluated cut-off value for detecting clinically meaningful sleep problems based on receiver operating characteristics analysis.

Based on the PGI scale, 161 patients (30.0%) did not reported any sleep problems. Factor analysis revealed almost the same factor structure described by the original PDSS-2 validation study. Cronbach's alpha was 0.863 and all item had good item-total correlation. PDSS-2 demonstrated high convergent validity with Non-Motor Symptoms Scale and Clinical Global Impression-Severity and non-motor part of MDS-UPDRS, and divergent validity with age, gender, education-level, disease-duration and Hoehn-Yahr Stages. Presence of sleep problems was identified by scores >10.5 points on PDSS-2 (sensitivity: 85.3%, specificity: 60.8%, diagnostic accuracy: 78.1%); whereas scores >19.5 points indicated marked sleep-related problems (specificity: 68.5%, sensitivity: 78.0%, diagnostic accuracy: 74.3%).

Independent and cross-cultural validation of patient reported outcomes is essential to confirm or reject the findings obtained by the developers of the scale. Our results demonstrate that fundamental clinimetric properties of the PDSS-2 are satisfactory.

INTRODUCTION

Recently the non-motor symptoms (NMS) of Parkinson's disease (PD) have been increasingly recognized as major burden of quality of life[1, 2]. Among the NMS, sleep-related problems are one of the most important and troublesome. Therefore, screening for sleep-problems and measuring their severity is of great clinical importance. However, sleep-related problems are certainly multidimensional. For example, sleep-disturbances in PD might equally be due to PD-related problems (e.g. troublesome nighttime OFF symptoms, hallucinations, rapid eye movements sleep behavioral disorder -RBD, or restless legs syndrome -RLS) and other issues not specific for PD (e.g. arousals caused by sleep apnea syndrome or nocturia).

Based on the systematic review and evaluation of sleep-related rating scales by the Movement Disorders Society Task Force[3], only a few scales were found to be appropriate for the PD population. Although the original Parkinson's Disease Sleep Scale (PDSS) [4] was recommended by the MDS Task Force, they identified some weaknesses of the scale including the inability to specifically identify and measure sleep apnea, RBD and RLS problems. To overcome these disadvantages, a new scale, the Parkinson's Disease Sleep Scale 2nd version (PDSS-2), was developed and published in 2011[5]. It is composed of 15 items evaluating three domains. Each item has a 5 point Likert-type scale ranging from 0: "Never" to 4: "Very often" (except for item 1 which is reversed). Each domain consists of clusters of five questions (Motor symptoms at night: 4, 5, 6, 12 and 13; PD symptoms at night: 7, 9-11 and 15; and Disturbed sleep: 1-3, 8 and 14)[5]. Symptoms on each domain can be scored in the range of 0-20 points; whereas, the sum of the 15 responses gives the total score of PDSS-2 with the maximum value of 60 points and higher scores meaning more nocturnal disturbance.

The PDSS-2 scale was validated on 113 PD patients in three centers in three different countries (United Kingdom, Germany and Austria). Clinimetric properties of the scale were confirmed by factor analysis, internal consistency, test-retest reliability, convergent and discriminative validity, and precision analyses. Based on their findings, the authors stated that PDSS-2 was a reliable, valid, precise and potentially treatment-responsive tool for measuring sleep problems in PD[5]. Therefore, the usage of PDSS-2

is recommended for screening and grading the severity of sleep problems in PD [6]. Additionally, the clinical usefulness of PDSS-2 was also demonstrated in many clinical studies. First, PDSS-2 was utilized in a double-blind, placebo-controlled trial assessing the efficacy of rotigotine on nocturnal disabilities[7]. Recently the responsiveness of PDSS-2 was also demonstrated after various therapeutic interventions including levodopa/carbidopa intestinal gel[8] infusion and bilateral subthalamic deep brain stimulation[9].

The objective of the present study was to perform an independent and intercultural validation of the PDSS-2 following the principles of the Classical Test Theory [10].

MATERIALS AND METHODS

Patients

In this nation-wide cross-sectional multicenter study 537 consecutive patients fulfilling the UK Brain Bank criteria for PD were enrolled in 9 centers. Each subject gave written consent in accordance with the ethical approval of National Ethical Committee (184/2013. 14437/2013/EKU). Each patient was examined by neurologists specialized in movement disorders. Portion of these patients (357/537) participated in the program of cultural adaptation and validation of the Movement Disorders Society-sponsored Unified Parkinson's Disease Rating Scale (MDS-UPDRS)[11] and Unified Dyskinesia Rating Scale[12] into Hungarian.

Patients with major neurocognitive decline were excluded from the study. Presence of dementia was defined as either having scores ≤125 points on Mattis Dementia Rating Scale (n=427)[13] and/or scores ≤22 points on Montreal Cognitive Assessment (n=537)[14-16]. Patients received their usual antiparkinsonian and other medication during the assessments. Subsequently, levodopa equivalent dosage calculations were performed[17].

Obtained rating scales

Severity of sleep problems were globally characterized by a Patients' Global Impression Scale (PGI) adjusted for sleep disturbances: no sleep problems, borderline/mild problems, moderate problems, marked problems and severe problems.

The PDSS-2 was translated according to approved translation standards into Hungarian (NK and BF) and back-translated into English (PA). Subsequently the original English and the back-translated English versions were compared[18].

Besides PDSS-2, socio-demographic and PD-related data, the Hungarian validated versions of MDS-UPDRS[11], PDQ-39[19] and Epworth Sleepiness Scales (ESS)[18, 20] were obtained. As being part of the MDS-UPDRS, the original Hoehn-Yahr Scale (HYS) was also taken to detect the overall severity of PD[21]. Because data from these scales were categorical, non-parametric tests were applied. Data were summarized at University of Pécs (by KH and NK).

Descriptive data analysis

As the items of most applied scales were ordinal variables, medians with interquartile range (IR, 25^{th}-75^{th} percentiles) were calculated. Because a score of 0 means symptom-free condition, the prevalence of each item was based on the portion of subjects having the score >0 point on that particular item. For variables following the normal distribution (e.g. age, disease-duration), medians ± standard deviations (SD) were also calculated.

Data quality was defined as the proportion of computable data. The criterion for acceptable amount of missing data is <10%[22]. For acceptability the floor and ceiling effect should be kept <15%[23] and the skewness should range between -1 and +1[24].

Factor analysis

Before the structure of the scale was explored by a factor analysis, the value of Kayser-Meyer-Olkin measure of sampling accuracy (KMO) was calculated. A KMO>0.60 is a minimum requirement; whereas, KMOs >0.90 are considered as excellent for factor analysis. We accepted only those factors having an eigenvalue >1 and a Scree test for factor analysis.

Reliability

In the clinimetrics, reliability is the overall consistency of a measure. A measure is said to have a high reliability if it produces similar results under consistent conditions[10]. In our study the internal consistency was evaluated by three approaches:

- Cronbach's α (should be >0.70)[25]
- corrected item-total correlation (should be >0.30 for each item)
- item homogeneity coefficient (should be >0.30).

Because the test-retest reliability of the Hungarian PDSS-2 was previously reported elsewhere[26], in this independent validation project we did not include the assessment of the test-retest properties of the scale.

Validity

Validity of an assessment is the degree to which it measures what it is supposed to measure. Therefore, it corresponds to how a measurement is well-founded and accurately describes the real world[10]. In our study the construct validity was evaluated by three different methods:

- Convergent validity: Convergent validity refers to the degree to which a measure is correlated with other measures that it is theoretically predicted to correlate with[10]. The total score and the subscores of PDSS-2 were compared to the PGI, Non-Motor Symptoms Scale (including the Sleep Subscale), MDS-UPDRS and PDQ-39. For correlation, Spearman's rank correlation coefficients were calculated. The values of correlation coefficients can indicate weak (0-0.299), moderate (0.300-0.599) and high (0.600-1.000) association[27].
- Internal validity. The correlation between the domains (subscales) should not be too low (r_S<0.300) or too high (r_S>0.700) either[28].
- Discriminative validity. Discriminative validity tests whether concepts or measurements that are supposed to be unrelated are, in fact, unrelated[10]. It is well-known, that the prevalence

and/or the severity of sleep-problems depend on age, sex[29, 30], education level, disease-duration and Hoehn-Yahr Staging[31]. Therefore, we tested the discriminative validity of PDSS-2 against these factors.

Precision

Precision of the PDSS-2 was estimated by standard error of measurement (SEM), where the value of SEM should be less than the half of the standard deviation.

Receiver operating characteristic (ROC) curve

In order to establish a cut-off value for the total score of PDSS-2, which can reliably differentiate the presence or absence of sleep-related problems, we applied ROC analysis. Patients were categorized by the PGI value (no problems at all vs. presence of sleep-disturbances with any degree). This categorization served as the state variable and PDSS-2 total score as the test variable. The best cut-off value was estimated as the point on the ROC curve closest to the point of (0,1). It was calculated as the minimum value of the square root of $(1\text{-sensitivity})^2+(1\text{-specificity})^2$. Besides, area under the curve, specificity, sensitivity, positive and negative predictive values (PPV and NPV, respectively) and diagnostic accuracy were calculated for the best cut-off value. Subsequently, we also tried to calculate a threshold value for discriminating marked sleep problems from mild-moderate sleep-problems based on the PGI value (having marked and severe sleep problems vs. having mild and moderate sleep disturbances).

Statistical analysis

All statistical analyses were carried out using IBM SPSS software package (version 21, IBM Inc., Chicago, USA). Statistical significance level was set to 5%. Because the SPSS Suite did not have built-in functions for calculating positive and negative predictive values, we utilized the syntax available on the IBM website (http://www-01.ibm.com/support/docview.wss?uid=swg21483380, assessed on Jan 15, 2013).

RESULTS

Demographic and PD-related clinical data

The subject population consisted of 537 non-demented PD patients. The clinical characteristics are demonstrated in **Table 1**.

Descriptive measurements

Based on the PGI scale, 161 patients (30.0%) did not report any sleep problems; whereas, 114 patients (21.3%) had mild/borderline, 96 (17.9%) had moderate, 133 (24.8%) had marked and 33 (6.0%) had severe sleep problems (**Table 1**).

Only 9 patients had a total score of 0 on PDSS-2. The prevalence of PDSS-2 items varied differently: Item 7 (hallucinations) had the lowest prevalence (16.9%), whereas, item 8 (nocturia) had the highest (88.6%, **Table 2**). Frequency of scores, median, 25^{th} and 75^{th} percentile values are shown in **Table 2**. Data quality was excellent for all PDSS-2 items **(Table 3)**

Factor analysis

The KMO value was sufficiently high (0.884) to enable a factor analysis. The Scree-test supported a one- or a three-factor solution explaining 28.9% and 38.9% of the variance, respectively. Using Principal Component Analysis extraction method with Varimax rotation, we identified almost the same factor structure as it was originally described (**Table 4**). Only item 8 “Nocturia” had somewhat different profile: It had almost identical loading for both “PD symptoms at night” and “Disturbed sleep” domains.

Reliability analysis

The value of Cronbach's α for the domains of the PDSS-2 varied between 0.715-0.748; whereas, for the total score it was 0.863 (**Table 3**). All the items reached the 0.30 threshold value for item-total correlation (**Table 3**). Item homogeneity index values were acceptable for all subdomains and the total score of PDSS-2.

Validity and precision

Table 5 shows the convergent validity for PDSS-2. The total score of PDSS-2 demonstrated high (>0.600) Spearman's rank correlation coefficient with other scales measuring sleep (PGI, Sleep section of NMSS) or any closely related constructs (Non-motor Aspects of Experiences of Daily Living part of MDS-UPDS, total score of NMSS, PDQ-39 Summary index). The internal validity for the subdomains of PDSS-2 was acceptable (r_S values in the range of 0.300-0.700, **Table 5**). As far as the discriminative properties were considered, all the domains and the total score significantly differed between males and females and among various age groups, education-levels, disease-duration, Hoehn-Yahr Staging and PGI groups ($p<0.01$ and $p<0.001$, Kruskal-Wallis tests).

The precision were acceptable for both the domains and the total score of PDSS-2 (**Table 3**)

ROC analysis

The cut-off value which best discriminated the presence of sleep disturbances from the absence was 10.5 points; therefore a total score ≥11 points on PDSS-2 may suggest the presence of clinically meaningful sleep-problems in PD. This cut-off value has sensitivity of 85.3%, specificity of 60.8%, PPV of 83.6%, NPV of 64.1% and diagnostic accuracy of 78.1%. The area under the curve was 0.810, whereas the ROC analysis yielded the statistical significance level ($p<0.01$).

The best cut-off value indicating the presence of marked sleep-problems was 19.5 points (specificity: 68.5%, sensitivity: 78.0%, PPV: 56.7%, NPV: 83.9% and diagnostic accuracy: 74.3%).

DISCUSSION

The aim of the present study was to develop the cross-cultural adaptation of the PDSS-2 and assess the fundamental clinimetric properties of the scale according to the principles of the Classical Test Theory.

Concerning the descriptive properties, the obtained data quality was excellent and skewness was satisfactory for all subdomains of the scale. The ceiling effect was also negligible for all the domains of the PDSS-2. While the "Motor symptoms" and "PD symptoms" subscales had relatively high, the "Disturbed

sleep" subdomain and the total score of the PDSS-2 had acceptable floor-effect. Although the presence of a high floor or ceiling effect may be an indicator for poor acceptability or faulty content validity and may also negatively influence the reliability and sensitivity of the measurement, we suspect other issue in the background. Because many patients (n=161, 30% of the examined population) did not have clinically meaningful sleep-problems these moderately high floor-effect values (18.3% and 18.1%) might be due the characteristics of the studied sample and not attributable to the scale itself. This assumption is further supported by the fact that the whole PDSS-2 scale (the total score) had only a negligible floor effect (1.7%).

Based on the sufficiently high KMO value, the performed factor analysis revealed almost an identical factor structure reported in the original validation study of PDSS-2. We observed only one minor issue about item 8 called "Nocturia". This item had almost the same loadings for both "PD symptoms at night" and "Disturbed sleep" domains (0.310 and 0.316, respectively). Moreover, nocturia is one of the most frequent phenomenon in sleep disturbances associated with PD. It can be caused by both PD-related and PD-unrelated problems. In some cases the PD symptoms (especially in OFF states) can produce urgency and dysuria as well as nocturia. However, obesity, cardiac failure, sleep apnea are the most important unrelated issues capable of producing nocturia[32]. Therefore, it is not surprising that the "Nocturia" item might similarly load in the "PD symptoms at night" and "Disturbed sleep" domains of PD. In our opinion, this issue might be considered as only a minor change from the original factor structure.

Concerning the reliability of the scale, we obtained satisfactory results. The internal consistency of the PDSS-2 was acceptable with alpha indexes clearly exceeding the threshold value of 0.70. Total score reached an alpha value higher than 0.8 indicating its usefulness for individual comparisons. All items surpassed the threshold value of 0.30 for the item-correlations. Because the independent validation of reproducibility of PDSS-2 was reported elsewhere [26], in this study we did not evaluate the test-retest validity of the scale. That study demonstrated sufficiently high values for both the Intra-class and Lin's Concordance Correlation Coefficients (0.782 and 0.799, respectively, for the total score of PDSS-2) indicating good reproducibility.

As assumed, the convergent validity between the PDSS-2 and other scales measuring similar constructs was satisfactory. The Spearman's rank correlation coefficients indicated high correlation with the PGI, the Sleep section of NMSS, the total score of NMSS and the Non-motor Experiences of MDS-UPDS. Similarly to the original validation study[5], we also observed high correlation between PDSS-2 and PDQ-39 Summary Index, an indicator of the contribution of sleep problems to impaired health-related quality of life. Similarly to the original PDSS-2 validation study, we also revealed low correlation between the PDSS-2 (nocturnal problems) with ESS (daytime sleepiness) and neurocognitive tests.

PDSS-2 showed satisfactory discriminative ability to differentiate based on gender, and between patients grouped according to age decades, education-levels, PD duration and HYS. (**Table 6**).

The PDSS-2 subscales also correlated with each other to a moderate/high level into the standard limits for internal validity (r_S=0.3-0.7, **Table 5**). The standard error of measurement values were suggestive of a high precision for all components of the scale.

As far as the authors are aware of, only a single study is published on the cut-off value for PDSS-2 differentiating clinically meaningful sleep disturbances. Suzuki and coworkers reported an optimal PDSS-2 cut-off to be 14 or 15 points for identifying poor sleepers using Pittsburgh Sleep Quality Index >5 points[33]. Based on our results, total scores higher than 10 points are indicative of sleep disturbances and identify subjects whose problems need further investigation. This discrepancy may be due to the different cultural background of the study population (Japanese vs. Hungarian), number of included patients (146 vs. 537) and different anchors applied (Pittsburgh Sleep Quality Index vs. PGI). Because sleep habits are considerably variable among different cultures, we suggest that distinct cut-off scores should be validated for particular PD populations.

We also calculated a threshold value for indicating the presence of marked sleep-problems. This additional cut-off value may be clinically useful for categorizing the degree of sleep-disturbances.

The strength of our study is its multicenter nature involving a large population of non-demented PD patients. However, we also have to admit some weaknesses. A major limitation of the current validation

study is the lack of polysomnography assessment (which should be regarded as better concurrent validity criterion). Polysomnographic data could provide interesting additional information; however, these data are not mandatory for performing a cross-cultural validation of an existent scale and determining the cut-off score. Another limitation of our study is the exclusion of demented patients even though that cognitively impaired PD subjects may have apparently more disturbances with sleep quality. We decided to exclude demented patients form this study, because in our opinion severe dementia might interfere with the reliability of PDSS-2 data. We assumed that severely demented patients (<125 points on Mattis Dementia Rating Scale) might not fill the PDSS-2 forms as accurately as it should be, which might have a negative impact on data quality. To compensate this weakness, we tried to evaluate any possible relationship between the scores on neurocognitive tests and PDSS-2. However, we could not identify clinically meaningful correlation between the scores of MDRS and PDSS-2 (Table 5).

CONCLUSIONS

Patient reported outcomes and self-completed questionnaires are widely used for patient assessment, follow-up and making clinical decisions in both clinical practice and research. Validation of adapted scales is important to assure the usefulness of the instrument in the setting in which it will be applied. The most important indicators for the quality of a scale are the reliability, validity and responsiveness. Because the replication of outcomes is a highly desirable scientific need, the independent validation of patient reported outcomes is essential to confirm or reject the findings obtained by the developers of the scale. Our results demonstrate that the fundamental clinimetric properties of the Hungarian validated version of PDSS-2 are satisfactory and confirm those of the original study[5].

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2. Statistical Analysis: A. Design, B. Execution, C. Review and Critique;
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Table 1. Clinical characteristics of the study cohort (n=537)

Characteristics	Mean±SD/number of patients	Percentage
Age	66.8±9.9	
Education years	11.8±3.3	
Sex	313 males	58.3%
Disease-duration	8.1±7.7	
Fluctuation	200	37.2%
Fluctuation years	5.3±4.2	
Presence of dyskinesia	198	36.8%
Presence of Dementia	0	0.0%
MDS-UPDRS Non-motor Aspects of EDL	14.2±7.6	
MDS-UPDRS Motor Aspects of EDL	15.5±9.2	
MDS-UPDRS Motor Examination	36.9±17.6	
MDS-UPDRS Motor Complications	4.5±3.7	
MDS-UPDRS Total Score	70.9±31.7	
Hoehn-Yahr stage I	31	5.8%
Hoehn-Yahr stage II	302	56.2%
Hoehn-Yahr stage III	137	25.6%
Hoehn-Yahr stage IV	53	9.9%
Hoehn-Yahr stage V	14	2.5%
Non-Motor Symptoms Scale	62.7±43.9	
Montreal Cognitive Assessment (n=537)	24.2±3.4	
Mattis Dementia Rating Scale (n=427)	137.1±14.2	
PDQ-39 Summary index	25.2±15.4	
Levodopa equivalent dosage (mg)	359.7±444.7	
Without antiparkinson medication	28	5.2%
Levodopa treatment	382	71.1%
Dopamine agonist treatment	296	55.1%
Levodopa and dopamine agonist combination treatment	235	43.7%
COMT- inhibition treatment	208	38.7%
MAO-inhibition treatment	117	21.8%
Anticholinergic therapy	10	2.2%
Deep brain stimulation therapy	73	13.6%
Levodopa/carbidopa intestinal gel infusion therapy	11	2.0%
Antipsychotic medication	11	2.0%
Sedative medication usage	39	7.3%
Severity of sleep disturbances –not present	161	30.0%
Severity of sleep disturbances –borderline/mild	114	21.3%
Severity of sleep disturbances –moderate	96	17.9%
Severity of sleep disturbances –marked	133	24.8%
Severity of sleep disturbances –severe	33	6.0%

Presence of dementia was defined as having scores ≤125 points on Mattis Dementia Rating Scale and/or scores ≤22 points on Montreal Cognitive Assessment.

Table 2. Prevalence, frequency of PDSS-2 items, domains and total score.

Item	Name of item	Prevalence	Frequency of score 0	Frequency of score 1	Frequency of score 2	Frequency of score 3	Frequency of score 4	Median	Percentile 25th	Percentile 75th	Mean	SD
1	Bed sleep quality	69.3%	165	136	118	71	47	1	0	2	1.4	1.3
2	Difficulties falling asleep	55.5%	239	99	99	65	35	1	0	2	1.1	1.3
3	Difficulties staying asleep	67.8%	173	90	96	95	83	2	0	3	1.7	1.5
4	Restlessness of legs and arms at night	52.7%	254	86	90	76	31	1	0	2	1.1	1.3
5	Urge to move legs and arms	52.0%	258	91	85	74	29	1	0	2	1.1	1.3
6	Distressing dreams at night	45.3%	294	107	96	26	14	0	0	2	0.8	1.1
7	Distressing hallucinations at night	16.9%	446	50	26	9	6	0	0	0	0.3	0.7
8	Nocturia	88.6%	61	114	111	123	128	2	1	3	2.3	1.3
9	Uncomfortable and immobility at night	48.4%	277	77	69	75	39	0	0	2	1.1	1.4
10	Pain in arms and legs	51.0%	263	95	88	62	29	1	0	2	1.1	1.3
11	Muscle cramps in arms and legs	58.5%	223	137	112	43	22	1	0	2	1.1	1.1
12	Painful posturing in the morning	41.2%	316	78	71	46	26	0	0	2	0.9	1.2
13	Tremor on waking	46.2%	289	79	68	61	40	0	0	2	1.1	1.3
14	Tired and sleepy after waking in the	70.6%	158	143	121	73	42	1	0	2	1.5	1.3
15	Snoring or difficulties in breathing	32.4%	363	80	66	17	11	0	0	1	0.6	1.0
	PDSS Motor domain	81.7%	98					4	1	8	5.0	4.4
	PDSS PD symptoms domain	81.9%	87					3	1	6	4.2	3.7
	PDSS disturbed sleep domain	97.2%	15					8	4	11	8.0	4.6
	PDSS Total score	98.3%	9					16	8	24	17.1	10.8

Table 3.Acceptability, reliability and precision of the PDSS-2.

	Motor symptoms domain	PD symptoms domain	Disturbed sleep domain	Total score
Data quality (%)	100	100	100	100
Skewness	0.773	0.811	0.353	0.568
Ceiling effect (%)	0.2	0.2	0.2	0.2
Floor effect (%)	18.3	18.1	2.8	1.7
Cronbach's α	0.748	0.715	0.736	0.863
Item-total correlation	0.389-0.678	0.339-0.649	0.355-0.532	NA
Item homogeneity	0.320	0.400	0.390	0.490
Mean	4.987	4.172	7.972	17.130
Standard deviation	4.402	3.712	4.589	10.808
Precision (standard error of measurement)	1.123	1.224	1.122	2.459

Table 4. Results of the factor analysis (three-factor solution)

Item	Name of item	Motor symptoms at night	PD symptoms at night	Disturbed sleep
1	Bed sleep quality	.151	.100	.767
2	Difficulties falling asleep	.281	.143	.698
3	Difficulties staying asleep	.148	.243	.838
4	Restlessness of legs and arms at night	.726	.271	.244
5	Urge to move legs and arms	.785	.163	.255
6	Distressing dreams at night	.410	.317	.088
7	Distressing hallucinations at night	.218	.239	.122
8	Nocturia	-.052	.306	.316
9	Uncomfortable and immobility at night	.306	.679	.061
10	Pain in arms and legs	.480	.620	.169
11	Muscle cramps in arms and legs	.470	.614	.153
12	Painful posturing in the morning	.740	.264	.049
13	Tremor on waking	.311	.154	-.049
14	Tired and sleepy after waking in the morning	.198	.260	.491
15	Snoring or difficulties in breathing	.351	.469	.096

Extraction Method: Principal Component Analysis. The items belonging to individual factors are highlighted by gray background.

Table 5. Convergent validity and internal validity of PDSS-2.

	PDSS Motor symptoms	PDSS PD symptoms	PDSS Disturbed sleep	PDSS Total score
CGI-S	.418**	.394**	.718**	.618**
NMS I Cardiovascular	.386**	.357**	.271**	.392**
NMS II Sleep	.530**	.507**	.550**	.627**
NMS III Mood	.433**	.402**	.407**	.493**
NMS IV Hallucinations	.226**	.272**	.152**	.248**
NMS V Memory	.252**	.258**	.210**	.282**
NMS VI Gastrointestinal	.292**	.316**	.221**	.325**
NMS VII Urinary	.262**	.300**	.390**	.378**
NMS VIII Sexual	.041	.002	.072	.047
NMS IX Miscellaneous	.323**	.317**	.239**	.345**
NMS Total	.512**	.502**	.517**	.607**
MDS UPDRS Non-motor EDL	.577**	.551**	.590**	.683**
MDS UPDRS Motor EDL	.528**	.543**	.413**	.582**
MDS UPDRS Motor Examinations	.290**	.264**	.183**	.294**
MDS UPDRS Motor Complications	.426**	.424**	.348**	.467**
MDS UPDRS Total	.503**	.488**	.409**	.554**
PDQ-39 Mobility	.477**	.493**	.397**	.538**
PDQ-39 ADL	.491**	.452**	.337**	.499**
PDQ-39 Emotional well being	.498**	.499**	.411**	.551**
PDQ-39 Stigma	.443**	.330**	.264**	.396**
PDQ-39 Social support	.319**	.325**	.304**	.371**
PDQ-39 Cognition	.414**	.390**	.301**	.434**
PDQ-39 Communication	.359**	.354**	.273**	.382**
PDQ-39 Bodily discomfort	.619**	.617**	.409**	.640**
PDQ 39 Summary index	.621**	.590**	.460**	.655**
ESS Total	.327**	.420**	.268**	.388**
Montreal Cognitive Assessment	-.178	-.227	-.182	-.232
Mattis Dementia Rating Scale	-.072	-.121	-.024	-.082
PDSS Motor		.692**	.526**	.862**
PDSS PD	.692**		.519**	.844**
PDSS disturbed	.526**	.519**		.826**
PDSS Total	.862**	.844**	.826**	

The table reports Spearman's rank correlation coefficients. *p<0.05. **p<0.01. ***p<0.001. Items having high correlation with PDSS-2 total score are highlighted.

Table 6. Discriminative validity of PDSS-2.

		Motor symptoms domain		PD symptoms domain		Disturbed sleep domain		PDSS Total Score	
		Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Sex	Males	4.6	± 4.0	4.0	± 3.8	7.7	± 4.3	16.4	± 10.2
	Females	5.8	± 4.6	4.8	± 3.9	8.4	± 4.6	18.9	± 11.4
	Kruskal-Wallis test	0.010		0.017		0.119		0.017	
Age	<50 years	3.9	± 3.9	2.6	± 3.1	6.5	± 4.6	12.9	± 10.4
	50-59 years	6.6	± 4.5	5.2	± 4.0	8.3	± 4.3	20.2	± 10.5
	60-69 years	5.0	± 4.2	4.5	± 3.8	8.1	± 4.8	17.6	± 11.1
	70-79 years	4.7	± 4.4	3.8	± 3.6	8.1	± 4.6	16.6	± 10.6
	≥80 years	4.0	± 4.7	3.7	± 3.6	7.7	± 3.7	15.4	± 10.3
	Kruskal-Wallis test	0.010		0.020		0.037		0.007	
Education (years)	0-8	5.8	± 4.7	5.0	± 3.9	8.8	± 4.4	19.6	± 11.1
	9-12	5.1	± 3.9	4.4	± 3.5	7.9	± 4.2	17.3	± 9.7
	>12	4.4	± 4.2	3.6	± 3.8	7.4	± 4.5	15.5	± 10.9
	Kruskal-Wallis test	0.014		0.001		0.038		0.001	
Disease duration	<5 years	4.0	± 4.1	3.0	± 3.2	6.4	± 4.7	14.4	± 10.2
	5-9 years	5.1	± 4.5	4.4	± 3.9	8.2	± 4.8	17.7	± 11.2
	10-14 years	5.7	± 4.3	5.0	± 3.7	7.9	± 4.3	18.7	± 10.7
	≥15 years	6.1	± 4.3	5.3	± 3.8	8.9	± 4.0	20.3	± 10.0
	Kruskal-Wallis test	p<0.001		p<0.001		0.033		p<0.001	
HYS	1	3.2	± 3.2	2.5	± 2.4	5.7	± 3.8	11.4	± 7.4
	2	4.3	± 4.0	3.4	± 3.3	7.4	± 4.3	15.1	± 9.8
	3	6.1	± 4.9	5.0	± 3.9	8.9	± 4.7	20.0	± 11.7
	4	6.4	± 4.5	6.6	± 4.3	10.1	± 4.8	23.1	± 10.9
	5	7.9	± 5.1	6.1	± 4.0	8.5	± 5.1	22.5	± 12.4
	Kruskal-Wallis test	p<0.001		p<0.001		p<0.001		p<0.001	
CGI-S	0	2.7	± 3.4	2.5	± 2.8	4.1	± 2.9	9.3	± 7.6
	1	4.1	± 3.8	3.4	± 3.1	6.5	± 3.1	14.0	± 7.6
	2	6.0	± 4.1	4.4	± 3.2	9.2	± 3.3	19.6	± 8.3
	3	7.3	± 4.7	6.3	± 4.1	11.5	± 3.6	25.1	± 10.4
	4	8.5	± 4.1	8.9	± 4.2	14.4	± 3.6	30.8	± 9.8
	Kruskal-Wallis test	p<0.001		p<0.001		0.033		p<0.001	