

A PSYCHOMETRIC EVALUATION OF THE REVISED SCOPA DIARY CARD IN PARKINSON'S DISEASE PATIENTS

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BACKGROUND

- Parkinson's disease (PD) is associated with well known motor symptoms, such as tremor and impaired balance. However, PD is also associated with a vast range of non-motor symptoms, such as cognitive impairment, excessive sweating and sleep disturbance. After several years of dopaminergic therapy, most patients experience fluctuations in both motor and non-motor symptoms.
- The recurrence of symptoms, often tied to medication "wearing-off", is commonly referred to as "off-time". Because "off-time" occurrences vary and can occur multiple times in a day, measurement relies on a diary format.
- The Scales for Outcomes in Patients with Parkinson's disease Diary Card (SCOPA-DC) is a daily diary designed to measure motor impairment in PD patients with fluctuating symptoms [1]. Previous qualitative research has evaluated the validity of the SCOPA-DC with findings supporting the expansion of the SCOPA-DC to measure non-motor symptoms [2].

OBJECTIVES

The current research examined the factor structure and psychometric properties of the revised SCOPA-DC.

METHODS

Study Design

A sample of adults from the U.S. age ≥ 30 with self-reported doctor-confirmed PD were recruited, screened, and consented online from a Knowledge Networks panel [3].

Inclusion criteria: ever experienced resting tremors and at least one of the following symptoms due to their Parkinson's disease: slowed ability to start and continue movements; rigidity or the inability to complete a movement, stiffness; difficulty with balance, instability; stooped, forward-leaning posture; freezing or sudden, brief inability to move the feet. **Exclusion criteria:** self reported history of brain surgery to treat PD symptoms; declined consent.

The following instruments were used to collect data in the online part of the study:

- Demographic and clinical self-report
- 12-Item Short Form Health Survey, version 2 (SF-12v2)
- Parkinson's Disease Questionnaire-8 (PDQ-8)
- Wearing off Questionnaire -9 (WOQ-9)

The following materials were mailed to eligible participants:

- Revised SCOPA-DC (completed 7 times per day for 3 consecutive days)
- Instructional DVD
- Feedback questionnaire

Scoring

Item scores were evaluated for the 11 symptom items (4 motor and 7 non-motor) in the revised SCOPA-DC by summing responses over the 21 time periods. This 3-day sum score was transformed to a 0–100 scale. Scale scores were evaluated by taking the average of the 3-day item scores for items within the same scale. Higher scores indicate greater severity.

RESULTS

Sample Characteristics

A total of 165 respondents completed their baseline assessment. Out of these, 61% (101) completed and returned the revised SCOPA-DC. Key demographic and clinical characteristics are presented in Table 1.

Table 1. Sample Characteristics (N=101)

		N	(%)
Age	Mean (SD)	66.3	(12.5)
Gender	Male	51	(50.5)
Race	White, Non-Hispanic	89	(88.1)
	Black, Non-Hispanic	5	(5.0)
	Hispanic	4	(4.0)
	Other	3	(2.9)
Diagnosed with PD	less than 1 year	20	(19.8)
	1 year or more.	81	(80.2)
Average "off-time"	Number of years, mean (SD)	7.4	(5.4)
	None	15	(14.9)
	1-25% of the day	58	(57.4)
	26-100% of the day	28	(27.7)
Currently taking Levodopa		62	(61.4)
How long have you been taking Levodopa?	less than 1 year	11	(17.7)
	1 year or more.	51	(82.3)

Factor Structure (Table 2)

CFA models for the hypothesized 2-factor structure resulted in goodness of fit indices that remained above cutoff values for acceptable model fit and EFA suggested that a 3-factor structure was a better fit.

The 3-factor structure indicated conceptually distinct domains of impairment:

- Factor 1 consisted of items concerning **mobility** impairments.
- Factor 2 represented symptoms that interfere with common daily activities and assess general **physical functioning**.
- Items in factor 3 fell strictly into the sphere of **psychological** impairment.

Table 2. Standardized Factor Loadings from Alternative Confirmatory Factor Analyses Models

Revised SCOPA-DC Item	Two-Factor Model [†]		Three-Factor Model		
	Factor 1	Factor 2	Factor 1	Factor 2	Factor 3
01. Walking	0.82		0.79		
02. Changing position	0.92		0.98		
03. Use your hands	0.68			0.74	
04. Uncontrollable movements	-			0.67	
05. Feelings of exhaustion or fatigue		0.80		0.77	
06. Difficulty concentrating or remembering		0.76			0.95
07. Feelings of anxiety or panic		0.59			0.75
08. Unexplained pains		0.78		0.80	
09. Difficulty swallowing		-		-	
10. Frequent or urgent urination		0.69		0.72	
11. Sweating too much		0.58		0.56	
	CFI/TLI	0.94 / 0.91		0.97/0.96	
	RMSEA (90% confidence interval)	0.09 (0.05, 0.13)		0.06 (0.00, 0.10)	
	SRMR	0.06		0.05	

[†] This model was obtained after model refinement: items 4 and 9 were excluded; items 6 and 7 were allowed to be correlated.

CFI=Comparative Fit Index, TLI=Tucker-Lewis Index, RMSEA=Root Mean Square Error of Approximation, SRMR=Standardized Root Mean Residual. Threshold values indicating good fit: CFI/TLI $\geq .95$; RMSEA $< .06$; SRMR $< .09$.

Factor Structure

Confirmatory Factor Analysis (CFA) was conducted with the robust maximum likelihood (MLR) estimator in Mplus 5.1. Due to sample size limitations, the stability of results obtained from factor analyses was evaluated using a method akin to k-fold cross validation [4], whereby the total sample was divided into 10 subsets of approximately equal size and factor models were evaluated by excluding each subset in turn. Goodness-of-fit was assessed using recommended goodness-of-fit indices and guidelines [5] and model refinement was undertaken by examining modification indices and magnitude of factor loadings.

Two CFA models were evaluated:

- 2-factor model based on one motor symptoms domain and one non-motor symptoms domain.
- 3-factor model derived from exploratory factor analysis (EFA) results.

Psychometric Indicators

Item-total correlations (corrected for overlap) ≥ 0.40 and small ($< 10\%$ increase) alpha-removed statistics were considered indicative of sufficient correlation with the underlying trait.

Coefficient alpha and model-based reliability were evaluated against the following criteria: ≥ 0.90 is excellent and ≥ 0.80 is sufficient [6].

Correlations with the PDQ-8 Summary Index (SI), the percentage of symptoms from the WOQ-9 and the summary scores of the SF-12v2 were evaluated to assess convergent and discriminant validity.

Known-groups validity analysis [7] was conducted by comparing mean scale scores across groups based on the absence (*stable*) or presence (*fluctuators*) of "off-time", at baseline.

Psychometric Indicators

Item-scale correlations indicated that each item was more strongly correlated with the hypothesized domain than with the other domains (Table 3).

Item-deleted Cronbach's Alpha indicated that most items contributed similarly to the scale (Physical Functioning scale only; Table 3).

All three scales showed good to excellent reliability.

The scales of the revised SCOPA-DC showed good convergent validity properties (Table 4).

Differences in mean scale scores (Table 4) between *stable* and *fluctuators* reached statistical significance for the Psychological Functioning Scale, but were consistently lower among *stable* participants for all 3 scales.

Table 3. Item-Scale Correlations and Reliability for Three-Factor Model

	Mobility	Physical Functioning	Psychological Functioning	Cronbach's Alpha	Cronbach's Alpha - item deleted
Mobility				0.87	
01. Walking	0.77	0.59	0.51		†
02. Changing position	0.77	0.67	0.55		†
Physical Functioning				0.86	
03. Use your hands	0.63	0.81	0.50		0.83
04. Uncontrollable movements	0.37	0.72	0.53		0.84
05. Feelings of exhaustion or fatigue	0.61	0.83	0.65		0.83
08. Unexplained pains	0.63	0.74	0.56		0.82
10. Frequent or urgent urination	0.43	0.77	0.56		0.83
11. Sweating too much	0.35	0.59	0.45		0.86
Psychological Functioning				0.83	
06. Difficulty concentrating or remembering	0.55	0.69	0.72		†
07. Feelings of anxiety or panic	0.47	0.56	0.72		†
Model Based Reliability	0.88	0.87	0.86		

[†]Cronbach's Alpha if item is deleted is not meaningful for a 2-item scale.

Table 4. Convergent/Discriminant and Known-Groups Validity

Revised SCOPA-DC Scale	Convergent / Discriminant Validity (Spearman Correlation Coefficients)				Known-Groups Validity Mean (SD) % "off-time"	
	PDQ-8 SI	WOQ-9 Percentage of Symptoms	SF-12 PCS	SF-12 MCS	Stable (absence of "off-time")	Fluctuators (presence of "off-time")
Mobility	0.60 [†]	0.45 [†]	-0.54 [†]	-0.47 [†]	21.7 (17.3) ¹	28.3 (21.7)
Physical Function	0.58 [†]	0.56 [†]	-0.46 [†]	-0.60 [†]	16.0 (17.6) ²	21.0 (15.5)
Psychological Function	0.62 [†]	0.48 [†]	-0.39 [†]	-0.58 [†]	9.2 (20.7) ³	15.9 (17.8)

PDQ8-SI = Parkinson's Disease Questionnaire 8; WOQ-9 = Wearing-Off Questionnaire 9; SF-12 = 12-Item Short Form Health Survey; = Physical Component Summary; = Mental Component Summary;

[†] = $p < 0.001$

¹ Not statistically significantly different from mean score of fluctuators ($p=0.202$, based on the t-test).

² Not statistically significantly different from mean score of fluctuators ($p=0.094$, based on the Mann-Whitney test).

³ Statistically significantly different from mean score of fluctuators ($p=0.023$, based on the Mann-Whitney test).

LIMITATIONS

Online recruitment of participants may have introduced bias by excluding individuals lacking appropriate skills and/or resources. Diagnosis of PD was self-reported which could have caused misclassification.

CONCLUSIONS

The results of the current study provided preliminary evidence that the following 3-domain structure best describes the measurement model of revised SCOPA-DC:

- Mobility (2 items)
- Physical Functioning (6 items)
- Psychological Functioning (2 items)

Patient feedback indicated that the Revised SCOPA-DC was meaningful to them, that the form was easy to complete and did not impose an excessive burden on their daily routine.

The revised SCOPA-DC is a valid instrument for measuring the impact of PD and the severity of symptom fluctuations.

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