scientific reports



OPEN

Psychometric properties of the Italian version of scale for outcomes in Parkinson's disease psychiatric complications in Parkinson disease

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The Scales for Outcomes in Parkinson's disease-Psychiatric Complications (SCOPA-PC) is a validated tool to score psychotic and compulsive symptoms in Parkinson's disease (PD). We translated into Italian the SCOPA-PC and evaluated its psychometric properties and clinical correlates in different subgroups of PD patients. The scale underwent translation, back-translation, and cognitive pretesting before being administered to a calculated sample of 135 PD patients. All patients underwent a clinical interview, motor evaluation, cognitive screening test, behavioral and functional scales. We explored SCOPA-PC feasibility, acceptability, internal consistency, convergent validity, known-groups validity, and test–retest reliability. The mean SCOPA-PC score was 1.99 ± 2.09 . The internal consistency was acceptable ($\alpha = 0.631$); corrected item-total correlation was > 0.45 for most items. The significant and moderate correlation of the SCOPA-PC with other tools evaluating psychiatric symptoms indicated adequate convergent validity of the scale. The factor analysis disclosed two factors, with total variance equal to 50.19%. The reliability of SCOPA-PC was high especially in cognitively preserved patients not on medications for dementia, depression, psychosis and anxiety. The SCOPA-PC is a rapid and reliable screening tool for assessing psychotic and compulsive symptoms in PD. Our data support a role for the SCOPA-PC as a screening scale in early, non-demented PD.

Keywords Behavioral symptoms, Parkinson disease, Psychiatric symptoms, Impulsive dyscontrol

Abbreviations

SCOPA-PC Scale for outcomes in Parkinson's disease-psychiatric complications PD Parkinson disease

Psychiatric disturbances are pervasive throughout all the course of Parkinson's disease (PD) from premotor to advanced stages¹⁻³. Depression, anxiety, apathy but also hallucinations, delusions and impulsive-compulsive disorders, can be detected in almost 90% of patients⁴⁻⁷ and have an impact on patients' health-related quality of life and activities of daily living⁸. The prevalence of each neuropsychiatric symptom varies in different stages of the disease often in relation to cognitive status⁹⁻¹¹.

Psychotic symptoms as hallucinations and delusions affect up to 30% of PD patients with a direct relationship with longer disease duration and worse cognitive performance^{12,13}. Hallucinations and delusions but also illusions and minor phenomena, such as presence and passage, are the most common psychotic manifestations in PD^{14–16}. The presence of hallucinations has been related to cholinergic deficit and considered an important predictor of dementia and mortality^{17,18}. Indeed, the amount and type of dopaminergic therapy can represent a trigger for psychotic symptoms in fragile patients^{19,20}. The prevalence of impulse control disorders (ICD) has been estimated in about 15% in patients receiving parkinsonian treatment²¹. The ICD prevalence increases with longer disease duration especially for eating disorders²² while some ICD as sexual impulse control disorders are more common in men with PD⁹.

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Despite the importance of psychotic symptoms in PD, a spoonful of tailored rating scales is available. By modifying the Parkinson Psychosis Rating Scale (PPRS) with the addition of an item on compulsive behaviour, Visser et al. ²³ proposed the SCales for Outcomes in Parkinson's disease-Psychiatric Complications (SCOPA-PC), that evaluates of severity of both psychotic and compulsive behavior in PD.

The SCOPA-PC is a rapid 7-item questionnaire administered to researcher for patient with the help of caregiver²³. To date, translations in languages other than English and data on the psychometric properties of the SCOPA-PC in PD are available for a few countries as Spain²⁴, Brazil²⁵, Argentina²⁶ and France²⁷.

Given the high clinical and research significance of a validated tool able to reliably assess psychotic and compulsive symptoms in patients with PD, we aimed to undertake a translation and cross-cultural adaptation of the SCOPA-PC into Italian language²³.

Hence, we conducted a study aimed to validate the cross-culturally adapted Italian version of the SCOPA-PC among native PD patients, adding new information on its clinimetric properties.

Methods Study design

We conducted a translation and cross-cultural adaptation of the SCOPA-PC following published guidelines for this kind of studies in the field²⁸. Authorization to use and adapt the original SCOPA-PC for research purposes was obtained from the International Parkinson and Movement Disorder Society (MDS). The project was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and was approved by the central Ethics Committee (number 2023/18986; 2023- November-22). All patients gave their informed consent prior to enrolment.

SCales for outcomes in PArkinson's disease-psychiatric complications (SCOPA-PC) and procedure to obtain the Italian version

The SCOPA-PC consists of seven items, investigating hallucinations, illusions and Misidentification of person, paranoid ideation (persecutory and/or jealous type), altered dream phenomena, confusion (impaired attention, memory, orientation in time, place or person, or incoherence of speech), sexual preoccupation and compulsive behaviour (shopping/gambling). Each item is rated on a 3-point Likert scale (0 = absent, 1 = mild, 2 = moderate, 3 = severe).

The total score, resulting from the sum of each symptom, has a range from 0 to 21, with higher scores reflecting more severe psychotic complications²³.

The English version of the SCOPA-PC was translated into Italian by one of the authors who is fluent in English (MP) and subsequently back-translated by a native English speaker fluent in Italian. A cognitive pretesting was conducted to evaluate the intelligibility of all questions and instructions and to gather feedback regarding the task's difficulty, as well as participants' interest, attention span, and any discomfort experienced during the scale administration. The provisional translated scale was administered to 10 PD patients by 2 evaluators external to the translator team, who collected questions and doubts from participants. These were incorporated into the revisions and retested until major issues were resolved. Following the cognitive pretesting phase, additional adjustments were made to the forward and back-translations if necessary. After enhancing the quality of the translations and considering the cognitive pretesting results, the final version for validation study was obtained which is displayed at https://www.movementdisorders.org/MDS-Files1/PDFs/Rating-Scales/SCOPA_PC_Italian_Final.pdf.

Participants and clinical assessment

PD, Italian native speaker patients diagnosed according to the MDS clinical criteria were consecutively enrolled²⁹, between December 2022 and December 2023, at the Center for Neurodegenerative diseases (CEMAND) of the Department of Medicine, Surgery and Dentistry, "Scuola Medica Salernitana" of the University of Salerno, Italy. Around 18 (between 15 and 20) cases per scale item was ensured. Therefore, the inclusion of at least 105 patients was planned. We excluded patients that presented dementia according to Diagnostic and Statistical Manual of Mental Illnesses (DSM-5)³⁰.

All patients were requested to complete the Italian version of the SCOPA-PC which is administered by a researcher, with help of caregivers²³.

The Montreal Cognitive Assessment battery (MoCA) was used to evaluate global cognition. Furthermore, patients' caregivers were requested to complete:

- The Questionnaire for Impulsive-Compulsive Disorders in Parkinson's Disease—Rating Scale (QUIP-RS), that measures the impulsive compulsive disorders³¹;
- The Italian version of Neuropsychiatry Inventory (NPI), that assesses both the frequency and severity of behavioural abnormalities, such as delusions, hallucinations, agitation and depression³²;
- The Italian version of Parkinson's Disease- Cognitive Functional Rating Scale (PD-CFRS) reported on website Movement Disorders Society and subsequently validated by Garon³³, that assesses functional limitations caused by cognitive impairment, reducing the influence of motor impairment.

Disease severity was evaluated with the MDS-sponsored version of the Unified Parkinson's disease rating scale part III (MDS-UPDRS-III) and the Hoehn and Yahr stage (H&Y). Ongoing medications were recorded including the use of antipsychotic, benzodiazepines, cholinesterase-inhibitors and memantine, antidepressants, and the dopaminergic treatment was transformed in levodopa equivalent daily dose (LEDD) according to prespecified formula³⁴.

To evaluate the stability of the Italian version of the SCOPA-PC (test–retest reliability), a subgroup of 30 patients (22.2%) repeated the scale 3 months after the first evaluation.

Statistical analysis

A descriptive analysis was used to study the distribution of demographic and clinical features of the recruited sample. Comparison between groups was run with t-test, Mann–Whitney, Kruskal–Wallis tests or chi square, as appropriate.

The following psychometric properties were explored for the SCOPA-PC total score: acceptability, reliability, and construct validity. Acceptability was considered appropriate for each SCOPA-PC item if there were \leq 5% of missing value and for total score if there were \leq 15% of the lowest and highest possible scores (floor and ceiling effect). Moreover, skewness of total (limits, -1 to +1) was determined. Reliability was evaluated by means of Cronbach's alpha. A value of \geq 0.60 was considered acceptable. Scaling assumptions referring to the correct grouping of items and the appropriateness of their summed score were checked using corrected item-total correlation (standard \geq 0.40).

Precision was evaluated by computing the standard error of measurement (SEM=SD $\sqrt{1 - Cronbach}$); a SEM value $\leq 1/2$ standard deviation was taken as the criterion of acceptable precision.

The SCOPA-PC dimensionality was investigated through exploratory factor analyses using the Principal Component Analysis. Appropriateness of the analyses was tested by Bartlett Test of Sphericity (standard < 0.05) and Kaiser–Meyer–Olkin Measure (KMO) of sampling adequacy (meritorious or better \geq 0.70). A minimum loading of 0.40 was used as a criterion for factor relevance, whereas item redundancy was considered if item load on several factors by > 0.40. To confirm the adoption of "the most adequate" model, a clinical guidance was considered.

The Pearson's correlation was used to check construct validity of the SCOPA-PC total score. Convergent validity was verified by correlating the SCOPA-PC total score with the total score and items of the QUIP-RS and the NPI as well as other demographic and clinical variables (age, education, disease duration, LEDD, H&Y). Divergent validity was measured correlating SCOPA-PC with MDS- UPDRS- III. We also analysed correlations between SCOPA-PC items and MOCA total score and QUIP-RS items. Values equal or greater than 0.60 were considered high correlation, a coefficient between 0.40 and 0.59 is considered moderate, lower than 0.2 is low correlation. We also determined the absolute reliability of the SCOPA-PC (i.e. the extent to which the scores remain the same across time or situations) and the paired Wilcoxon test was used to compare the mean SCOPA-PC score at baseline and follow-up. Subsequently, to examine the relative stability of the SCOPA-PC score, the intraclass correlation coefficient (ICC) between SCOPA-PC on the first and second administration was computed.

The SCOPA-PC known-groups convergent validity was explored with Mann-Whitney or Kruskal-Wallis tests after grouping patients by sex (men and women), disease duration (two groups split according to median disease duration, 4 years), treatment category (with or without at least one medication among antipsychotic, benzodiazepines, cholinesterase-inhibitors and memantine, antidepressants), cognitive status (two groups split according to the MoCA median value, 21).

All analyses were performed using SPSS for Windows, version 23.0. with significance value set at 0.05.

Results

Sample characteristics

One hundred and thirty-five patients were enrolled for the present study. The demographic and clinical features of the enrolled cohort are reported in Table 1. For the entire sample, the frequency distribution of symptoms were: hallucinations (14.81%), illusion and paranoid ideation (15.6%), altered dream phenomena (45.2%), confusion (51.9%), Sexual preoccupation (7.40%) and Compulsive behaviour (8.14%).

SCOPA-PC clinimetric properties

Feasibility and acceptability

One hundred percent of data were totally computable and there was no missing value (0%). An overview of distribution of the SCOPA-PC total is shown in Fig. 1.

In the whole sample, the floor effects was observed for the SCOPA-PC total score (lower possible score = 0, 28.9%; highest possible score = 13, 0.7%). The skewness of SCOPA-PC total score was 1.955 (criterion: -1 to +1).

Internal consistency and test-retest reliability

Cronbach's alpha coefficient was 0.631 and, thus, it was considered acceptable for internal consistency.

All items, except item 6 (r=0.167, p=0.052), presented significant correlations with the SCOPA-PC total score (r>0.45, p<0.001).

The standard error of measurement (SEM) value for SCOPA-PC total score was 0.209 [SEM=SD $\sqrt{1 - \text{Cronbach's alpha}}$].

Regarding absolute stability of SCOPA-PC, the Wilcoxon test showed no significant difference between the SCOPA-PC score at baseline compared with follow-up (z = -1,40, p = 0.161). The ICC between scores on the first and second administration was 0.664 [0.35–0.82, confidence interval for 95%; p = 0.001].

Dimensionality

All 7 items of the SCOPA-PC were deemed appropriate for factorial analysis, since KMO was 0.712. In addition, Bartlett's test was 133.360 (p<0.001) indicating that the data satisfied the preliminary assumption to run factorial analysis.

Sample characteristics (N=135)					
		Minium	Maximum		
Age, years (mean ± SD)	69.51 ± 9.60	35	85		
Sex, Men, N (%)	94 (69.6)				
Education, years (mean ± SD)	10.96 ± 5.11	0	19		
Disease duration, years (mean ± SD)	6.45 ± 4.90	1	20		
MDS-UPDRS-III (mean ± SD)	26.86 ± 11.39	7	62		
H&Y (mean ± SD)	2.05 ± 0.21	1.5	3		
MoCA, total score (mean ± SD)	20.22 ± 5.74	6	30		
SCOPA-PC (mean ± SD)	1.99 ± 2.09	0	13		
LEDD, mg (mean ± SD)	341.42 ± 252.94	0.0	1231.0		
Acetylcholinesterase inhibitors, N (%)	8 (5.9)				
Tradozone, N (%)	4 (3.0)				
Selective Serotonin Reuptake Inhibitors, N (%)	7 (5.2)				
Atypical neuroleptics, N (%)	3 (2.2)				
Benzodiazepine, N (%)	14 (10.4)				
Memantine, N (%)	0 (0)				

Table 1. Demographic and clinical features of the enrolled cohort. Data are reported in mean ± standard deviation, unless otherwise specified. $H \not \sim Y$ Hoehn and Yahr scale, LEDD levodopa equivalent daily dose, MoCA Montreal cognitive assessment battery, N, number, SCOPA-PC scales for outcomes in Parkinson's disease-psychiatric complications, SD standard deviation, MDS-UPDRS-III movement disorder society-sponsored version of the unified Parkinson's disease rating scale part III.

The factor analysis disclosed two factors with eigenvalues greater than 1.0 and the visual inspection of the screen plot confirmed the presence of two factors (Table 2). The total variance explained by the extracted factors was 50.19%. All seven items showed factor loading greater than 0.45 and less than -0.45.

The first factor load items 1, 2, 3, 4, 5, 7 and its factor loading were between 0.486 and 0.781. It was related to hallucinations, illusions, paranoid ideation, altered dream phenomena, confusion and compulsive behaviour, thus, this factor was named Psychotic and compulsive complications, Cronbach's alpha was 0.687. The second factor loaded only item 6 and its factor loading was 0.860. It was related to sexual preoccupation, and, thus, it was named Sexual preoccupation. The variance explained by Factor 1 was 34.104% and by Factor 2 was 16.095%.

There was not significant correlation between two factors (p = 1.00).

Cronbach's alpha coefficient for Factor 1 (all item except item 6) ($\alpha = 0.687$) was comparable to Crobach's alpha coefficient of all items of SCOPA-PC ($\alpha = 0.631$).

Convergent and divergent construct validity

The SCOPA-PC total score showed convergent validity with increased QUIP-RS total score (r = 0.54, p < 0.001) and NPI (frequency X severity) total score (r = 0.54, p < 0.001), with moderate correlations. No correlation was reported between SCOPA-PC and MDS- UPDRS-III (p = 0.539). There were significant correlations among specific items of SCOPA-PC and specific items of both QUIP-RS and NPI items (Table 3). There was a low significant negative correlation between SCOPA-PC total score and MOCA total score (r = -0.211, p < 0.05) and a significant positive moderate correlation between SCOPA-PC total score and PD-CFRS total score (r = 0.491, p < 0.001).

The SCOPA- PC did not correlate with age, education, disease duration, MDS-UPDRS-III, LEDD, H&Y (p > 0.05).

Known-groups validity

The frequency distribution of symptoms according to disease duration, presence/absence of drugs and MoCA score are reported in Fig. 2.

Differences of SCOPA-PC total was significant for treatment category (patients on at least one medication among acetylcholinesterase inhibitors, memantine, antidepressants, atypical neuroleptics and benzodiazepines versus patients without, 2.77 ± 1.79 versus 1.77 ± 2.12 , p = 0.021) and cognitive status (patients with MoCA ≤ 21 versus patients with MoCA ≥ 22 , 2.18 ± 1.86 versus 1.47 ± 1.50 , p = 0.020) but not for sex (p = 0.769) and disease duration (p = 0.637). However, when examining the frequency distribution of symptoms, altered dream phenomena (48.9%), confusion (47.9%) and illusion (14.9%) were the most frequent in men and confusion (61%), altered dream phenomena (36.6%) and paranoid ideation (22%) were the most frequent in women.

When examining internal consistency for different groups of patients, the Cronbach's alpha coefficient was found lower for patients on at least one drug among acetylcholinesterase inhibitors, memantine, antidepressants, atypical neuroleptics and benzodiazepines versus patients without (0.335 vs. 0.679), for patients with lower MoCA versus those with higher MoCA (0.471 vs. 0.501), for patients with longer disease duration versus those with shorter disease duration (0.291 vs. 0.738).

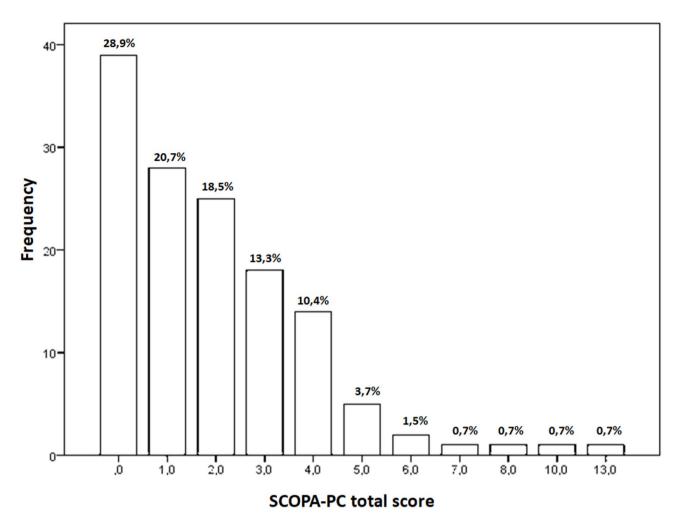


Fig. 1. Frequency distribution of the SCOPA-PC total score.

	Factor 1 Psychotic and compulsive complications	Factor 2 sexual preoccupation
Item 1. Hallucinations	0.781	
Item 2. Illusions	0.486	
Item 3. Paranoid ideation	0.771	
Item 4. Altered dream phenomena,	0.574	
Item 5. Confusion	0.543	
Item 6. Sexual preoccupation		0.860
Item 7. Compulsive behavior	0.551	
Variance explained	34.10%	16.09%
Cronbach's alpha	0.687	-

Table 2. Dimensionality of the SCOPA-PC according to factor analysis.

Discussion

The SCOPA-PC is an instrument specifically designed for the evaluation of severity of psychotic and compulsive behaviour in patients with PD. This study was aimed to translate and validate the scale in Italian language and adding new information on its clinimetric properties.

As a whole, the Italian SCOPA-PC acceptability was satisfactory. Data quality was excellent with 100% of data totally computable and the percentage of missing values was 0% for all items.

The skewness value was slightly higher than the standard limit (1.0). Such asymmetry may be due to the floor effect as almost one third of the sample scored 0. As a matter of fact, there is a consistent proportion of PD patients especially in the earliest phase of the disease without any psychotic or compulsive symptom. This

SCOPA-PC	Other scales and tests	r	p
Item 1. Hallucinations	NPI hallucinations	0.645	< 0.001
Item 2. Illusions	NPI hallucinations	0.392	< 0.001
Item 3. Paranoid ideation	NPI delusions	0.485	< 0.001
Item 5. Confusion	MoCA	- 0.445	< 0.001
Item 6. Sexual preoccupation	QUIP-rs sex	0.540	< 0.001
Item 7. Compulsive behavior	QUIP-rs gambling	0.771	< 0.001
Item 7. Compulsive behavior	QUIP-rs buying	0.748	< 0.001

Table 3. Convergent validity of the SCOPA-PC items, measure by Pearson's correlations. *MoCA* Montreal cognitive assessment battery, *NPI* neuropsychiatric inventory, *p p-value*, *QUIP-rs* Questionnaire for impulsive-compulsive disorders in Parkinson's disease–rating scale, *r* Pearson's coefficient, *SCOPA-PC* scales for outcomes in Parkinson's disease–psychiatric complications. Bold-typed values represent statistically significant findings.

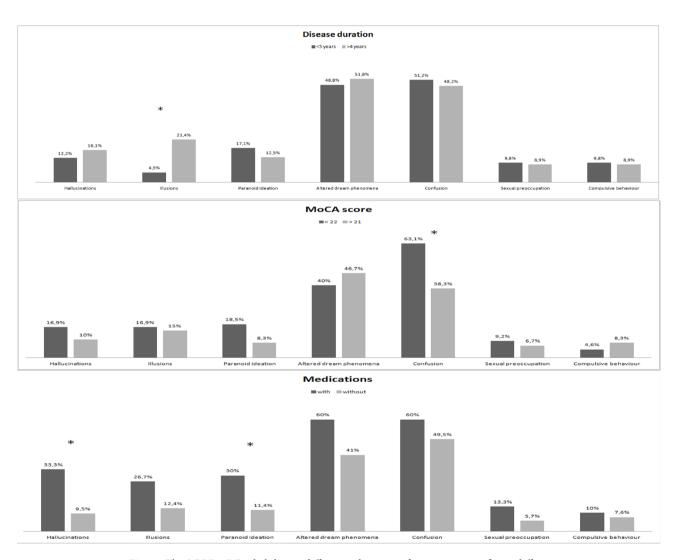


Fig. 2. The SCOPA-PC reliability in different subgroups of patients. * significant differences.

finding is inconsistent with Visser et al.' $study^{23}$ probably because their sample had longer the disease duration than ours.

The internal consistency of SCOPA-PC is acceptable (α = 0.631; item SCOPA-PC total score correlation \geq 0.40 for most items). All items presented a significant correlation with the total score except for item 6. Such lack of correlation may be due to the wide spectrum of meanings underlying sexual preoccupation behaviours such as: sexual dysfunction, sexual desire discrepancy with the partner after restored sexual desire, hypersexuality and compulsive sexual behaviour as part of impulse control disorders and sexual behaviour with underlying restless

genital syndrome³⁵. The SCOPA-PC item 6 is aimed to assess hypersexuality and compulsive sexual behaviour as part of impulse control disorders, however the other aspects may have an impact on patients' replies.

The degree of precision of measurement, expressed in terms of SEM, is adequate suggesting the SCOPA-PC values in our sample are an accurate estimation of the SCOPA-PC values in the PD population. Also, test–retest reliability of the SCOPA-PC total score is fair. Therefore, SCOPA-PC is a valid tool for assessing the presence and severity of psychotic and compulsive symptoms in PD.

To our knowledge this is the first SCOPA-PC validation study that performed factorial analysis. Our factor analysis revealed two factors that explained 50.19% of the total variance and that represented two dimensions of neuropsychiatric symptoms, both psychotic and compulsive complications (delusion, hallucination, confusion) and sexual preoccupation. Most of the total variance is explained by factor 1 which encompasses all items but item 6 (sexual preoccupation). As a matter of fact item 6 is responsible for a reduction of the level of reliability of the scale. Given sexual preoccupation is the least reported complain in our sample, we can not exclude it is either under-recognized or tends not to be reported due to a cultural issue. On the other hand, all items loaded in Factor 1 can frequently co-occur and be linked to common underlying networks including the orbitofrontal and ventromedial prefrontal cortex, the cingulate cortex, the amygdala and the uncinate fasciculus³⁶. However, we should also consider that the SCOPA-PC only includes sexual preoccupation among all the possible compulsive behaviors, as shopping/gambling, compulsive eating, hobbyism, or punding which were not included in the originally version of because their nature and relevance were not well established when that scale was proposed²³.

Our data demonstrate adequate convergent validity, as the SCOPA-PC total score showed significant association with QUIP-RS total score and NPI total score.

Regarding specific items and in line with Visser et al.²³, we found significant correlations between hallucinations, delusions, sexual preoccupation and compulsive behaviour in SCOPA-PC and the same items reported in NPI and QUIP-RS. Compared to the latter scales, the SCOPA-PC has the advantage of being short and rapid to administer. As such, it can be used as a screening tool to be combined with more detailed assessment instruments when needed.

The lack of correlation between SCOPA-PC item 4 (altered dream phenomena) and NPI sleep abnormalities revealed the different sleep features explored by the two scales. SCOPA-PC assessed only the presence of vivid or unpleasant dreams while NPI investigated sleep symptoms in terms of difficulty falling asleep, nocturnal awakenings and night-time agitation³².

When examining differences in specific groups of patients, we found higher SCOPA-PC scores in patients with worse cognitive status documented by lower MoCA scores and in patients taking at least one medication among antidementia, neuroleptics, antidepressants, benzodiazepines. Such data reinforce the known relationship between psychotic and compulsive symptoms and cognitive impairment. Noteworthy, there was no significant difference based on disease duration, supporting the interaction between psychosis and cognition is not necessarily mediated by longer disease duration^{3,17,18,22}. As a matter of fact our data support better SCOPA-PC reliability for patients with better cognitive performances and without specific treatment for dementia, psychosis, depression and anxiety. Such data further support the use of the SCOPA-PC as a screening tool in cognitively-preserved PD patients.

However, it is important also to note that the study has some limitations, such as the relatively small sample size, the lack of longitudinal evaluation and the use of English version of QUIP-RS. Therefore, further research is needed to confirm the results and evaluate the validity of the Italian SCOPA-PC in different clinical and cultural contexts. Giving the importance of neuropsychiatric symptoms in PD, efforts have been gathered to create a scale useful to measure them. In 2009, the Movement Disorder Society established a Task Force on Rating Scales in PD reviewed twelve psychosis scales/questionnaires and none of them was deemed adequate to capture the entire phenomenology of PD psychosis. The Task Force found that different scales may be more suitable for specific settings. For example the NPI is adequate to screen cognitively impaired PD population or when a caregiver is present, while the Schedule for Assessment of Positive Symptoms (SAPS), the Positive and Negative Syndrome Scale (PANSS), or Brief Psychiatric Rating Scale (BPRS) are more suitable for the cognitively intact PD population or when the patient is the sole informant. Also, the Clinical Global Impression Scale (CGIS) is suggested as a secondary outcome scale to measure change and response to treatment over time³⁷. The Parkinson Psychosis Rating Scale (PPRS) is the first scale specifically created for PD patients, it has a good reliability but it is validated in a small sample (N = 29) and it does not include impulse control disorders³⁸. The SCOPA-PC was designed by modifying the PPRS with the addition of an item on compulsive behaviour²³. Our data demonstrate that SCOPA-PC is a rapid and reliable screening tool for assessing psychotic and compulsive dysfunctions in PD. Its reliability increases when administered in cognitively-preserved patients not taking specific treatments for dementia, psychosis, depression and anxiety.

Data availability

The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

Received: 9 January 2025; Accepted: 19 May 2025

Published online: 24 May 2025

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Acknowledgements

We are grateful to Sue Ainscough for helping with the translation process.

Author contributions

All authors have contributed to this study: #1 Research project: A. Conception, B. Organization, C. Execution; #2 Statistical Analysis: A. Design, B. Execution, C. Review and Critique; #3 Manuscript Preparation: A. Writing of the first draft, B. Review and Critique; SC=1A, 2B, 2A, 2B, 3A, 3B AC=1C, 2C, 3A, 3B IC=1C, 3B MA=1C, 3B RB=1C, 3B CS=1C, 3B MA=3B PB=2C, 3B MP=1A, 2B, 2A, 2C, 3B.

Funding

This work was supported by the Italian Ministry of Health (GR-2019-12370133).

Declarations

Competing interests

The authors declare no competing interests with the present work. PB received consultancies as a member of the advisory board for Zambon, Lundbeck, UCB, Chiesi, Abbvie and Acorda. MP is supported by the Italian Ministry of Health and the Fondazione della Società Italiana di Neurologia. The other authors report no financial disclosures.

Ethics approval

The project was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. The Study Protocol was approved on 22.11.2023 by the Ethics Committee "Campania 2", the protocol number is 166/2021, All subjects agreed with a written consent form to the use of their anonymized data for research purposes, the study being approved by the local ethical committee. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this work is consistent with those guidelines.

Additional information

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