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ORIGINAL ARTICLE

Patient-reported impact of symptoms in schizophrenia scale (PRISS): Development and validation

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Abstract

Background: We report the psychometric properties of the Patient-Reported Impact of Symptoms in Schizophrenia Scale (PRISS), which assesses the impact of subjective experiences or qualia in outpatients with this condition.

Methods: A cross-sectional study was carried out in 162 patients diagnosed with schizophrenia in Spain. The PRISS measures the presence, frequency, concern and interference with daily life of self-reported experiences related to the main symptoms observed in these patients. The psychometric analysis included test-retest reliability, internal consistency and structural and convergent validity.

Results: The 28-item PRISS showed good test-retest reliability as 64.3% of the intraclass correlation coefficient values were between 0.40 and 0.79, which were statistically significant ($p < 0.01$). Analysis of the structural validity revealed a three-factor structure, (1) productive subjective experiences, (2) affective-negative subjective experiences and (3) excitation, which accounted for 56.11% of the variance. Of the Pearson's correlation coefficients analysed between the PRISS

and the Positive and Negative Syndrome Scale (PANSS), Scale for Assessment of Negative Symptoms (SANS) and World Health Organization Disability Assessment Schedule (WHO-DAS), 72.2% were statistically significant ($p < 0.05$) and ranged from 0.38–0.42, 0.32–0.42 and 0.40–0.42, respectively.

Conclusion: Our results indicate that the PRISS appears to be a brief, reliable and valid scale to measure subjective experiences in schizophrenia and provides valuable information complementary to clinical evaluation.

KEYWORDS

patient-reported outcome, patient-reported outcome measure, schizophrenia, subjective experiences

1 | INTRODUCTION

Since the beginning of the 21st century, there has been increasing interest in understanding how patients feel and are impacted by their symptoms and by the effects of care and treatment. Patient-reported outcomes (PROs) and qualia (perceptions of the quality of an experience) have become important measures of both clinical results and quality of care.[1] In a systematic review, Doyle et al. showed a positive association between patient-reported experience and the clinical effectiveness of the interventions delivered.[2] Patient-reported outcomes are also becoming a major issue in mental health. Recently, Aimola et al. concluded that the opinions of persons with severe mental disorders can provide very useful information about the quality of care they are receiving.[3]

To assess PROs, identifiable, valid and reliable patient-reported outcome measures (PROMs) are needed as tools to offer a more comprehensive view of the impact of care on the patient.[4] Different PROM instruments have been used in people with severe mental disorders. Millier et al.[5] reviewed the use of PROMs in schizophrenia and found 70 generic, mental health-specific or schizophrenia-specific instruments categorized in six main domains (health-related quality of life, insight, depression/feelings, treatment-related, illness symptoms and caregiver/family). After this review, a number of PRO scales in schizophrenia has been published. The Oxford Capabilities Questionnaire—Mental Health (OxCAP-MH) is a 16-item scale that covers domains of functioning and welfare and has been validated in patients with psychosis.[6,7] The Symptom Self-rating Scale for Schizophrenia (4S) is a 58-item scale that measures symptoms and their discomfort on an 11-point Likert scale.[8] It comprises six symptom subscales and two side effects scales: extra-pyramidal, nine items and autonomic, four items. It has been validated in hospital settings.[9]

Despite these significant advances in the development of PROMs in patients with schizophrenia, there is still a dearth of valid instruments to measure perceived experiences related to observed symptoms in outpatients with schizophrenia.

Significant outcomes

- The Spanish version of the Patient-Reported Impact of Symptoms in Schizophrenia Scale (PRISS) appears to be a valid and reliable questionnaire to assess patient self-reported experiences related to a set of common clinical symptoms of schizophrenia.
- The PRISS is a patient-reported outcome measure (PROM) that assesses the patient's perspective and provides valuable information complementary to clinical evaluation.
- The PRISS has good structural validity with items clustered into a three-factor structure: (1) productive subjective experiences, (2) affective-negative subjective experiences and (3) excitation.

Limitations

- Patient self-assessment of insight is not reported.
- Schizoaffective disorders and other schizophrenic spectrum disorders were excluded from this study.
- Validation was carried out in a Spanish-speaking sample, and additional testing will be needed in other languages.

1.1 | Aims of the study

The study aim was to develop and validate the Patient-Reported Impact of Symptoms in Schizophrenia Scale (PRISS), a brief scale that assesses the subjective impact of reported experiences related to main symptoms in patients with schizophrenia. This study reports the psychometric properties, test-retest reliability, internal consistency and construct validity (structural and convergent validity) of the scale in a clinical sample of outpatients with schizophrenia in Spain.

2 | METHODS

This validation study was carried out by a consortium of four Spanish research centres with prior experience in the standardization of tools for clinical evaluation in schizophrenia. The standardization of the PRISS was conducted in outpatient and community rehabilitation settings.

2.1 | Participants

The participants comprised 162 patients with a clinical diagnosis of schizophrenia (ICD-10 code F20),[10] assigned by the clinician responsible for the care of the patient. Ages ranged between 18 and 65 years. Participants were recruited from community mental health services in four provinces of Spain (Malaga, Barcelona, Girona and Cadiz). These facilities were described and classified according to the Description and Evaluation of Services and Directories for Long-Term Care (DESDE 2.0) system.[11] Individuals were excluded from the study if, according to the clinician primarily responsible for the care of the patient, they had an ongoing acute psychotic episode, a diagnosis of intellectual disability, severe substance use disorder, schizoaffective disorder or other schizophrenic spectrum disorders, including schizotypal personality disorder. Patients hospitalized in acute wards or treated with lithium therapy or patients with severe medical or neurological disorders were also excluded from the study. Participants completed all questionnaires in a single session, and a subgroup completed a retest in a second session. The local ethics committee of each centre approved the study procedures. All participants provided informed consent.

2.2 | Measures

To develop the PRISS, we followed a multi-stage process. First, we designed the questionnaire based on the most common symptoms in patients with schizophrenia. Items were selected to assess the three domains that are evaluated within the clinician-rated PANSS (Positive and Negative Syndrome Scale).[12,13] Each question of the PRISS was formulated in a series of iterative sessions by the team members that took into account the PANSS items.[14] As an example, the first question in the assessment of delusions was as follows: '*Have you had the feeling that a strange force has controlled your mind or has been trying to communicate with you in the past week?'* When the experience was present, respondents were asked to report its frequency on a 4-point Likert scale (1: almost never; 2: sometimes; 3: often; or 4: always). Then, patients were asked to report their level of concern (worry), and its interference in daily life on a 5-point Likert scale from 0 to 4 (0: No concern/No interference; 1: Mild/Slight; 2: Moderate; 3: Serious; 4: Extreme). The four characteristics of the PRISS (presence, frequency, worry and interference with daily life) were provided both for each item and as total scores.

A pilot study was conducted with 20 patients (five in each of the four participating centres) to verify the initial feasibility of the PRISS. This preliminary assessment revealed difficulties in filling in the questionnaire particularly in patients with low levels of literacy. Therefore, an interviewer-assisted procedure was designed to support interviewees who had reading difficulties. In these cases, the questions were read by the interviewer, who recorded the responses of the patient but provided no interpretation. The interviewers in the four centres were trained in the use of the PRISS. The PRISS was then administered to the sample from 01/08/2018 to 30/09/2019.

A complementary ad-hoc questionnaire recorded the following information: (1) sociodemographic characteristics: gender, age, civil status, education level, living arrangement details and characteristics of the mental health centre; (2) clinical data: number of psychiatric hospitalizations, age at first hospitalization, total duration of all episodes of hospitalization and psychological and pharmacological treatment.

Social and demographic characteristics were obtained directly from the patient. Clinical data were obtained from the clinician primarily responsible for the care of the patient. When additional missing information was required, the researchers consulted the patient's medical records.

To calculate the convergent validity of the PRISS, we administered the Spanish version of the PANSS, which showed good inter-rater reliability and modest internal consistency.[14] The PANSS items were evaluated by means of the PANSS interview and rated according to the definitions and criteria provided in the manual of the Spanish version.[15] In addition, we administered the alogia and apathy domains of the Scale for Assessment of Negative

Symptoms (SANS).[16,17] We did not administer the full SANS to avoid redundancy with the PANSS and to reduce the total completion time. Finally, we administered the World Health Organization Disability Assessment Schedule, version 2.0 (WHO-DAS 2.0),[18,19] which assesses six areas of functioning: (a) Cognition; (b) Mobility; (c) Self-care; (d) Getting along/interacting with other people; (e) Life activities; and (f) Participation/joining in community activities. The total score ranges from 0 to 100, where higher scores indicate greater disability.

An experienced clinician (a psychologist or a psychiatrist) conducted the PANSS, SANS and WHO-DAS in each centre. All interviewers were previously trained by experts in these questionnaires.

2.3 | Statistical analyses

We performed a descriptive analysis of the sociodemographic and clinical characteristics of the sample and ratings of the PRISS items. Imputation procedures were not applied to the analysis of PRISS items as missing data ranged between 0.6% and 2.5% for the PRISS items. The intraclass correlation coefficient (ICC) was used for the test-retest reliability analysis. The scale was re-administered to a subsample of 56 patients following the corrected sample size suggested by Bonett[20] to detect ICCs ≥ 0.7 with an amplitude of 0.2, for $\alpha = 0.05$ and $\beta = 0.2$. The second administration took place within two weeks of the first, and support was provided by the same interviewer when needed. ICC values were interpreted in accordance with the classification of Landis and Koch.[21]

The internal consistency of the scale was assessed using McDonald's omega[22] (values of 0.80 and over are considered satisfactory)[23] and Cronbach's alpha coefficients.[24] Cronbach's alpha values were interpreted as acceptable (0.6–0.79), good (0.8–0.9) and excellent (>0.9),[25] although values from 0.5 to 0.6 could be adequate in exploratory or pilot studies.[26]

We also assessed the construct validity of the PRISS. First, we explored its factor structure by using an exploratory factor analysis (EFA) and an orthogonal (varimax) rotation. Structural validity was established using a confirmatory factor analysis (CFA). To obtain factor solutions, we used the polychoric correlation matrix and robust maximum likelihood (MLR) methods. Four practical fit indexes were included to evaluate the model fit: Tucker-Lewis index (TLI), comparative fit index (CFI), root mean square error of approximation (RMSEA) and standardized root mean square residual (SRMR). Factor loadings of the items were interpreted following the suggestions of Tabachnick and Fidell.[27] A given item was assigned to a factor when its factor loading was ≥0.30. In order to choose the best factor structure, the clinical expertise and parsimonious criteria were also used, in addition to statistical criteria.

Convergent validity was assessed by examining the association between the PRISS and other clinical variables as well as between the PRISS and the PANSS, SANS and WHO-DAS 2.0, using kappa coefficients[28] and Pearson's correlation coefficients, interpreted according to Mukaka.[29] We also used the two-factor structure of negative symptoms (PANSS-2)[30,31] (1. diminished expression and 2. amotivation) as well as the factors of the PANSS-5 (1. negative, 2. positive, 3. excitation, 4. anxiety/depression, 5. cognitive)[32]

Except in the descriptive and test-retest reliability analysis, the PRISS presence and frequency were analysed together using a Likert scale from 0 to 4, where the value 0 indicates no presence and therefore no frequency, and the values 1 to 4 indicate the degree of frequency. We made this decision to simplify the results of the statistical analyses.

We used SPSS v24 and Mplus version 7.2[33] while employing a significance level of 0.05.

3 | RESULTS

3.1 | Participant characteristics

Seventy-seven per cent of the participants were men, and the mean age was 43.58 ± 10.96 years. Of these, 90.7% were single, 46.5% had completed primary education and 50% lived with their parents. At least one previous episode of hospitalization was reported in 88.3% of the sample, and the mean number of previous psychiatric hospitalizations was 5.30 ± 6.21. The mean age at first hospitalization was 26.76 ± 9.16 years. A total hospitalization period longer than 3 months were reported in 53.6% of the sample, and previous psychological treatment had been provided in 40.1%. The DESDE 2.0 system[11] was used to classify the community services: 39.5% of patients were attended in day centres, 37.0% in community residential services and 23.5% in outpatient services. The characteristics of the sample and the medication profiles are shown in Table 1.

3.2 | Descriptive analysis of PRISS items

The descriptive analysis of the PRISS revealed a lack of results in frequency, concern and interference with daily life in two items, 'Emotional withdrawal' and 'Lack of judgment and insight'. This was due to the questions being worded in an inverse way, which prevented continuation with the remaining questions (frequency,

TABLE 1 Sociodemographic and clinical characteristics of the sample

	n	%
Gender ($N = 162$)		
Men	125	77.1
Women	37	22.8
Mean age ($N = 162$) (years)		
Mean ± SD 43.58 ± 10.96		
Median, Range 44.50; 20–64		
Civil status ($N = 162$)		
Single	147	90.7
Married, separated, divorced or widowed	15	9.3
Educational level ($N = 161$)		
Without studies	11	6.8
Primary education	75	46.6
Secondary education or professional training	65	40.4
University degree	10	6.2
Living arrangement ($N = 162$)		
Parents	81	50.0
Own family	12	7.4
Alone	24	14.8
Residential services	39	24.1
Other	6	3.7
City and type of centres ($N = 162$)		
Barcelona ($N = 40$)		
Day services	19	11.7
Residential hospital services	17	10.5
Outpatient services	4	2.5
Cadiz ($N = 39$)		
Day services	15	9.3
Residential services	24	14.8
Malaga ($N = 41$)		
Day services	11	6.8
Residential services	7	4.3
Outpatient services	23	14.2
Girona ($N = 42$)		
Day services	19	11.7
Residential services	12	7.4
Outpatient services	11	6.8
Psychiatric hospitalization		
Previous episode(s) of hospitalization ($N = 162$)		
Yes	142	88.3
No	19	11.7
Number of hospitalizations ($N = 142$)		
Mean ± SD 5.30 ± 6.21		
Median; Range 3; 1–38		
Age at first hospitalization (years) ($N = 142$)		
Mean ± SD 26.76 ± 9.16		
Median; Range 24; 14–51		
Total hospitalization period ($N = 140$)		
<3 months	75	53.6
≥3 months	65	46.4
Psychological treatment ($N = 162$)		
Yes	65	40.1
No	97	59.9
Antipsychotic treatment ($N = 162$)		
Yes	161	99.4
No	1	0.6
Number of antipsychotic drugs ($N = 161$)		
Taking a single drug	79	49.1
Taking 2 drugs	62	38.5
Taking ≥3 drugs	20	12.4
Antidepressant treatment ($N = 162$)		
Yes	45	27.3
No	117	72.3
Hypnotic treatment ($N = 162$)		
Yes	35	21.6
No	127	78.4
Anxiolytic treatment ($N = 162$)		
Yes	76	46.9
No	86	53.1

concern and interference with daily life) for each item. This was detected in the statistical analysis phase, so these two items were excluded from the final version of the scale. The rest of the items were correctly worded. The validated Spanish version of the 28-item PRISS was translated into English by a bilingual translator and back-translated (into Spanish) by a second independent bilingual translator. The final 28-item PRISS (English version) is available in Annex 1. Figure 1 shows the visual analogue scale provided in the interviewer-assisted option.

We quantified the four characteristics of the PRISS as follows:

(i) Presence of perceived PRISS items: the absence or presence of each of the items of the PRISS (no = 0, yes = 1). In addition, the global ordinal PRISS score was examined as the total number of PRISS items experienced.

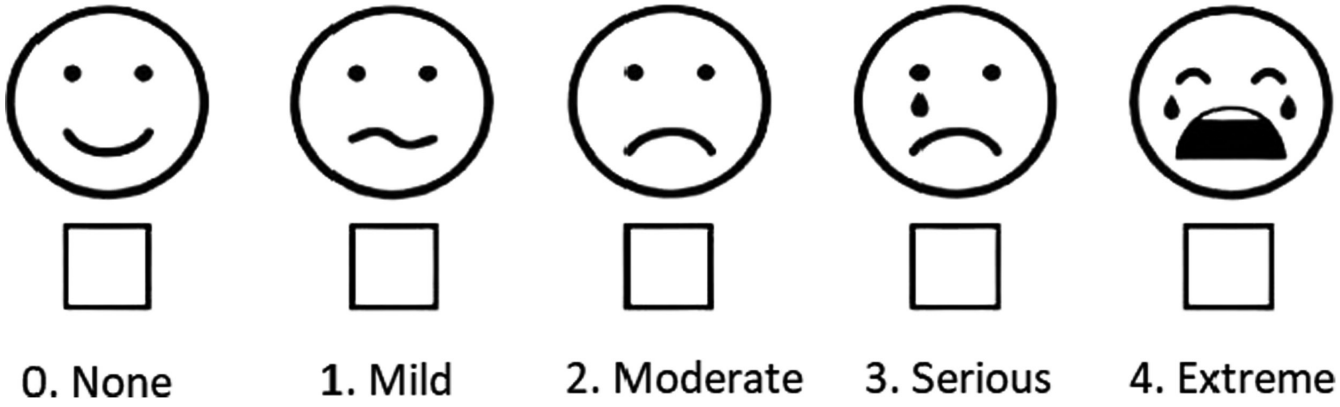

FIGURE 1 Visual analogue scale used in interviewer-assisted questionnaire

(ii) Frequency of the perceived PRISS items was analysed as a dichotomous variable categorized as infrequent (<3) or very frequent (≥3). Infrequent includes the following 4-point Likert scale codes: (1) almost never or (2) sometimes, and very frequent includes (3) often or (4) always.

(iii) Level of worry of the perceived PRISS items was also classified into two categories as little concern (<3) or much concern (≥3). Little concern includes the following 5-point Likert scale codes: (0) no concern or (1) mild or (2) moderate, and much concern includes (3) serious or (4) extreme.

(iv) Interference in daily life of the perceived PRISS items was also classified into two categories: less interference (<3) or greater interference (≥3). Less interference includes the following 5-point Likert scale codes: (0) no interference or (1) mild or (2) moderate, and much interference includes (3) serious or (4) extreme.

Support to complete the questionnaire was offered to the participants, and 54.3% preferred this option over taking the self-administered questionnaire. The mean time it took to complete the PRISS was 17 ± 9 min.

Table 2 shows the percentage of patients who reported each subjective experience. When an item was reported as present, the presence of other characteristics (frequency, concern and interference in daily life) occurring in the week before were also recorded. The experiences more frequently reported by patients were conceptual disorganization (positive experience), poor rapport (negative experience) and anxiety (general experience). Self-reported experiences of hallucinations, stereotyped thinking and somatic concerns showed the highest levels of frequency. Suspiciousness, stereotyped thinking and preoccupation were the reported experiences associated with the highest level of worry during the week before the interview. Finally, the highest level of interference in daily life was reported in suspiciousness, blunted affect and preoccupation.

3.3 | Test-retest reliability

The median time between test and retest (interquartile range) was 9 days (range: 7–14 days). The 28-item PRISS showed good test-retest reliability as 64.3% of the ICC values were between 0.40 and 0.79, which were statistically significant ($p < 0.01$). In addition, 92.9% of the ICC values for presence were statistically significant ($p < 0.01$) as were 85.7% of the ICC values for frequency, worry and interference in daily life ($p < 0.01$) (Table 2).

Test-retest reliability was not statistically significant for somatic concern: *'Have you been excessively worried about your physical health in the past week?'* (interference in daily life); mannerisms: '*Have you made unusual movements, gestures or postures in the past week?*' (frequency); disorientation: '*Have you had trouble determining what time of the day it was or where you were during the past week?*' (frequency, worry and interference in daily life); and poor impulse control '*Have you had trouble controlling your impulses in the past week?*' (worry).

3.4 | Construct validity

3.4.1 | Structural validity

Factor analyses were performed to explore the factor structure of the three characteristics of the PRISS. Results of the EFA revealed that three-, four- and five-factor solutions showed good statistical fit, whereas the three-factor solution also met the clinical expertise and parsimonious criteria. The CFA results confirmed a three-factor structure which accounted for 56.11% of the variance. Items of the PRISS corresponding to each factor—factor

TABLE 2 Description of characteristics of the items of the PRISS, test-retest reliability of the PRISS items and convergent validity between the PRISS items and the PANSS items

	Characteristics of the PRISS items $N = 162$								Kappa[e]
	Only for items with presence				Test-retest reliability $N = 56$				$N = 100$
	Presence	Frequency ≥3[a]	Worry ≥3[b]	Interference[c] ≥3[d]	Presence	Frequency ≥3[a]	Worry ≥3[b]	Interference[c] ≥3[d]	
Items of PRISS	n (%)	n (%)	n (%)	n (%)	ICC (CI95%)	ICC (CI95%)	ICC (CI95%)	ICC (CI95%)	PANSS
1. Delusions	48 (29.6)	17 (35.4)	18 (37.5)	20 (41.6)	0.65** (0.45; 0.78)	0.65** (0.46; 0.78)	0.64** (0.45; 0.78)	0.51** (0.28; 0.68)	0.358**
2. Conceptual disorganization	67 (41.4)	28 (41.8)	21 (31.3)	19 (28.8)	0.49** (0.26; 0.66)	0.50** (0.27; 0.67)	0.69** (0.52; 0.80)	0.58** (0.38; 0.73)	0.211*
3. Hallucinations	42 (25.9)	24 (57.1)	18 (42.9)	19 (45.2)	0.48** (0.26; 0.66)	0.33** (0.09; 0.54)	0.33** (0.08; 0.54)	0.34** (0.10; 0.55)	0.393**
4. Excitement	66 (40.7)	19 (28.8)	21 (31.8)	17 (25.8)	0.55** (0.34; 0.70)	0.64** (0.45; 0.77)	0.61** (0.42; 0.75)	0.70** (0.53; 0.81)	0.320**
5. Grandiosity	49 (30.2)	24 (49.0)	6 (12.2)	9 (18.4)	0.79** (0.67; 0.87)	0.75** (0.61; 0.85)	0.37** (0.12; 0.57)	0.70** (0.54; 0.81)	0.268**
6. Suspiciousness	55 (34.00)	26 (47.3)	29 (52.7)	27 (50.0)	0.63** (0.44; 0.77)	0.58** (0.37; 0.73)	0.67** (0.49; 0.79)	0.67** (0.50; 0.79)	0.233*
7. Hostility	26 (16.0)	3 (11.5)	12 (46.2)	7 (26.9)	0.62** (0.43; 0.76)	0.67** (0.49; 0.79)	0.75** (0.61; 0.85)	0.80** (0.68; 0.88)	0.101
8. Blunted affect	56 (34.6)	21 (37.5)	18 (32.1)	18 (32.1)	0.68** (0.51; 0.80)	0.55** (0.34; 0.71)	0.54** (0.32; 0.71)	0.58** (0.37; 0.73)	0.172
9. Poor rapport	66 (40.7)	33 (50.0)	17 (25.8)	15 (23.1)	0.55** (0.33; 0.71)	0.60** (0.40; 0.74)	0.56** (0.35; 0.72)	0.56** (0.35; 0.72)	0.065
10. Passive social withdrawal	56 (34.6)	24 (42.9)	15 (26.8)	17 (30.4)	0.59** (0.39; 0.74)	0.58** (0.38; 0.74)	0.58** (0.37; 0.73)	0.46** (0.23; 0.65)	0.100
11. Difficulty in abstract thinking	61 (37.7)	28 (45.9)	15 (24.6)	13 (21.3)	0.56** (0.34; 0.72)	0.67** (0.49; 0.79)	0.72** (0.56; 0.83)	0.69** (0.52; 0.81)	0.286**
12. Lack of spontaneity	62 (38.3)	28 (45.2)	17 (27.4)	17 (27.4)	0.36** (0.11; 0.57)	0.51** (0.29; 0.68)	0.46** (0.22; 0.64)	0.38** (0.13; 0.58)	0.249*
13. Stereotyped thinking	62 (38.3)	32 (51.6)	20 (32.3)	17 (27.4)	0.53** (0.32; 0.70)	0.52** (0.30; 0.69)	0.34** (0.10; 0.55)	0.37** (0.13; 0.58)	0.231*
14. Somatic concern	68 (42.0)	34 (50.0)	30 (44.1)	24 (35.8)	0.29* (0.03; 0.51)	0.48** (0.25; 0.66)	0.31* (0.05; 0.52)	0.16 (−0.10; 0.40)	0.340**
15. Anxiety	89 (54.9)	35 (39.3)	31 (34.8)	24 (27.0)	0.37** (0.13; 0.58)	0.40** (0.15; 0.59)	0.31** (0.06; 0.52)	0.39** (0.15; 0.59)	0.334**
16. Feelings of guilt	62 (38.3)	19 (30.7)	22 (35.5)	18 (29.0)	0.38** (0.13; 0.59)	0.47** (0.24; 0.65)	0.33** (0.08; 0.55)	0.37** (0.11; 0.58)	0.347**
17. Tension	45 (27.8)	12 (26.7)	10 (22.2)	10 (22.2)	0.40** (0.16; 0.60)	0.57** (0.36; 0.72)	0.60** (0.40; 0.74)	0.49** (0.26; 0.67)	0.112
18. Mannerisms	18 (11.1)	5 (27.8)	6 (33.3)	5 (27.8)	0.17 (−0.09; 0.41)	0.30* (0.03; 0.52)	0.58** (0.37; 0.73)	0.51** (0.29; 0.68)	0.019
19. Depression	75 (46.3)	22 (29.3)	28 (37.3)	22 (29.3)	0.72** (0.56; 0.82)	0.69** (0.52; 0.80)	0.74** (0.59; 0.84)	0.76** (0.62; 0.85)	0.264**
20. Motor retardation	58 (35.8)	14 (24.1)	17 (29.3)	16 (27.6)	0.41** (0.17; 0.60)	0.38** (0.13; 0.58)	0.54** (0.32; 0.70)	0.56** (0.34; 0.72)	0.119
21. Uncooperativeness	30 (18.5)	7 (23.3)	9 (30.0)	9 (30.0)	0.57** (0.36; 0.72)	0.35** (0.10; 0.56)	0.43** (0.19; 0.62)	0.53** (0.32; 0.70)	0.147
22. Unusual thought content	46 (28.4)	21 (45.7)	18 (39.1)	17 (37.0)	0.63** (0.44; 0.76)	0.49** (0.27; 0.67)	0.45** (0.21; 0.64)	0.44** (0.21; 0.63)	0.116

TABLE 2 (Continued)

	Characteristics of the PRISS items $N = 162$								Kappa[e]
	Only for items with presence				Test-retest reliability $N = 56$				$N = 100$
	Presence	Frequency ≥3[a]	Worry ≥3[b]	Interference[c] ≥3[d]	Presence	Frequency ≥3[a]	Worry ≥3[b]	Interference[c] ≥3[d]	
Items of PRISS	n (%)	n (%)	n (%)	n (%)	ICC (CI95%)	ICC (CI95%)	ICC (CI95%)	ICC (CI95%)	PANSS
23. Disorientation	24 (14.8)	7 (29.2)	7 (29.2)	6 (25.0)	0.40** (0.15; 0.60)	0.11 (−0.15; 0.36)	0.12 (−0.14; 0.37)	0.06 (−0.20; 0.31)	0.196**
24. Poor attention	76 (46.9)	34 (44.7)	18 (23.7)	20 (26.3)	0.30** (0.05; 0.51)	0.36** (0.11; 0.57)	0.23* (−0.01; 0.45)	0.37** (0.11; 0.58)	0.355**
25. Disturbance of volition	55 (34.0)	18 (32.7)	21 (38.2)	16 (29.1)	0.39** (0.15; 0.58)	0.28* (0.03; 0.50)	0.33** (0.09; 0.54)	0.29* (0.04; 0.51)	0.236*
26. Poor impulse control	31 (19.1)	9 (29.0)	11 (35.5)	11 (35.5)	0.52** (0.29; 0.69)	0.33** (0.08; 0.54)	0.21 (−0.05; 0.45)	0.25* (−0.00; 0.48)	0.054
27. Preoccupation	62 (38.3)	28 (45.2)	28 (45.2)	25 (40.3)	0.32** (0.07; 0.53)	0.28* (0.03; 0.50)	0.36** (0.11; 0.56)	0.32** (0.07; 0.53)	0.154
28. Active social avoidance	56 (34.6)	24 (42.9)	17 (30.4)	17 (30.4)	0.43** (0.19; 0.62)	0.46** (0.23; 0.65)	0.47** (0.23; 0.65)	0.47** (0.24; 0.65)	0.195*

Note: In some items, one or two responses were missing.

PRISS, Patient-Reported Impact of Symptoms in Schizophrenia Scale; ICC, Intraclass Correlation Coefficient.

[a] Frequency ≥3 refers to very frequent (often and always).

[b] Worry ≥3 refers to much concern (serious and extreme).

[c] Interference with daily life.

[d] Interference with daily life ≥3 refers to greater interference (serious and extreme).

[e] Agreement coefficient between the presence of each PRISS item and its corresponding PANSS item.

* $p < 0.05$.; ** $p < 0.01$.

TABLE 3 Factor structure of the PRISS, factor loadings and fit indexes obtained in CFA across the characteristics of the PRISS ($N = 162$)

	Presence-frequency			Worry			Interference with daily life		
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3
PRISS items	Productive experiences	Affective - negative	Excitation	Productive experience	Affective - negative	Excitation	Productive experiences	Affective - negative	Excitation
1. Delusions	0.79			0.89			0.79		
3. Hallucinations	0.83			0.86			0.86		
5. Grandiosity	0.67			0.85			0.80		
6. Suspiciousness	**0.80**				**0.82**		0.91		
13. Stereotyped thinking	0.62			0.68				**0.75**	
18. Mannerisms and posturing	0.64			0.72					**0.68**
21. Uncooperativeness	0.76			0.80				**0.76**	
22. Unusual thought content	0.79			0.83			**0.86**		
23. Disorientation	**0.64**				**0.79**				**0.76**
26. Poor impulse control	0.70			0.70					**0.67**
2. Conceptual disorganization		0.69			0.76			0.72	
8. Blunted affect		0.64			0.73			0.73	
9. Poor rapport		0.70			0.78			0.81	
10. Passive social withdrawal		0.62			0.68			0.73	
11. Difficulty in abstract thinking		0.64			0.70			0.70	
12. Lack of spontaneity		0.78			0.81			0.81	
15. Anxiety		0.61			0.62				**0.70**
16. Feelings of guilt		0.68			0.72				**0.82**
19. Depression		0.70			0.67				**0.75**
20. Motor retardation		0.53			0.57			0.62	
24. Poor attention		0.69			0.66			0.64	
25. Disturbance of volition		0.65			0.70			0.75	
27. Preoccupation		0.77			0.80				**0.80**
28. Active social avoidance		0.86			0.84			0.86	
4. Excitement			0.68			0.70			0.61
7. Hostility			0.74			0.81			0.83
14. Somatic concern			0.48			0.51			0.49

TABLE 3 (Continued)

PRISS items	Presence-frequency			Worry			Interference with daily life		
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3
	Productive experiences	Affective - negative	Excitation	Productive experience	Affective - negative	Excitation	Productive experiences	Affective - negative	Excitation
17. Tension			0.53			0.64			0.61
CFI	0.95			0.95			0.96		
TLI	0.95			0.95			0.96		
RMSEA	0.05			0.05			0.05		
SRMR	0.08			0.08			0.08		

Note: CFA, Confirmatory Factor Analysis; CFI, Comparative Fit Index; PRISS, Patient-Reported Impact of Symptoms in Schizophrenia Scale; RMSEA, Root Mean Square Error of Approximation; SRMR, Standardized Root Mean Square Residual; TLI, Tucker-Lewis Index.

Bold is used when items saturate in different factors according to the characteristics of the PRISS (presence-frequency, worry or interference).

'1' (productive experiences), factor '2' (affective-negative experiences) and factor '3' (excitation)—are shown in Table 3. The factor loadings between items and factors ranged from 0.48 to 0.91.

As a result of the CFA, most of the PRISS items included in each factor (1: productive experiences, 2: affective-negative experiences and 3: excitation) are matched in the three characteristics of the scale: presence-frequency, concern and interference.

The age of the participants had a statistically significant association with factor '3' (excitation) for presence-frequency ($r = -0.16$). The age of the participants at their first psychiatric hospitalization showed statistically significant correlations with factor '1' (productive experiences) in relation to presence-frequency ($r = -0.76$), worry ($r = -0.17$) and interference with daily life ($r = -0.20$).

All PRISS items except for suspiciousness and disorientation saturated on the same factors for both presence-frequency and worry characteristics, which indicates a very similar factor structure in these two characteristics. We did, however, find some discrepancies in the interference with daily life characteristic, in which factor '3' (excitation) included anxiety, feelings of guilt, depression and preoccupation. Goodness-of-fit index values ranged from 0.95 to 0.96 for the CFI and the TLI and were 0.05 and 0.08 for the RMSEA and the SRMR, respectively (Table 3).

The PRISS factors showed good test-retest reliability across the presence-frequency, worry and interference with daily life characteristics, with ICC values ranging from 0.52 to 0.80 for factor '1' (productive experiences), from 0.75 to 0.85 for factor '2' (affective-negative experiences) and from 0.81 to 0.87 for factor '3' (excitation factor). Factor '2' (affective-negative experiences) showed the highest internal consistency and reliability with McDonald's omega and Cronbach's alpha coefficients showing excellent and good values (0.92–0.93 and 0.88–0.91, respectively), followed by factor '1' (productive experiences) (0.83–0.91 and 0.85–0.86, respectively). Factor '3' (excitation) also showed acceptable values for McDonald's omega and good indexes for Cronbach's alpha (0.80–0.91 and 0.54–0.84, respectively) (Table 4).

3.4.2 | Convergent validity

We used the kappa coefficient to analyse the convergent validity of the presence of each PRISS item with its corresponding PANSS item. We recorded the scores for the PANSS items so that 3–7 = Presence and 1–2 = Absence. According to the kappa interpretation of Landis and Koch (1977),[21] the agreement between the items of the PANSS and the PRISS was fair (0.21–0.40) in half of the items and slight (0.01–0.20)

TABLE 4 Test-retest reliability (ICC, $N = 56$) and internal consistency reliability (McDonald's omega and Cronbach's alpha, ($N = 162$)) of the factors according to the presence-frequency, worry and interference characteristics of the PRISS.

	Presence-frequency			Worry			Interference with daily life		
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3
	Productive experiences	Affective - negative	Excitation	Productive experiences	Affective - negative	Excitation	Productive experiences	Affective - negative	Excitation
ICC	0.69	0.85	0.81	0.52	0.80	0.82	0.80	0.75	0.87
McDonald's omega	0.91	0.93	0.80	0.89	0.93	0.84	0.83	0.92	0.91
Cronbach's alpha	0.85	0.88	0.54	0.85	0.91	0.64	0.86	0.90	0.84

Note: ICC, Intraclass Correlation Coefficient; PRISS, Patient-Reported Impact of Symptoms in Schizophrenia Scale.

in the other half. Thus, no moderate, substantial or almost perfect correlation was found in any of the items (Table 2).

Of the Pearson correlation coefficients analysed between the PRISS and the PANSS, PANSS-2, SANS and WHO-DAS, 72.2% were statistically significant ($p < 0.05$) (Table 5).

According to the total score of the PRISS and the total score of the PANSS, statistically significant correlations were found (ranging from 0.38 to 0.42). The relationship between the two factors of the PANSS-2 and the corresponding items of the PRISS was analysed. Statistically significant correlations were observed between factor 1 (diminished expression) of the PANSS-2 and the respective items on the PRISS, which are blunted affect, poor rapport, lack of spontaneity and motor retardation in its three characteristics. Factor 2 (amotivation) of the PANSS-2 also had a statistically significant correlation with the passive social withdrawal and active social avoidance items of the PRISS in presence-frequency. The avolition-apathy dimension of the SANS had statistically significant correlations (ranging from 0.32 to 0.38) with the motor retardation item in the three characteristics. Finally, statistically significant correlations were found between the total score of the PRISS in the three characteristics and the WHO-DAS 2.0 (ranging from 0.40 to 0.42). The results are shown in Table 5.

The negative factor (1) of the PANSS-5 showed the highest correlation with factor '2' (affective-negative experiences) of the PRISS (ranged from $r = 0.37$to $r = 0.45$). In relation to the positive factor (2) of the PANSS-5, the highest correlation found was with factor '1' (productive experiences) of the PRISS associated with its interference with daily life ($r = 0.36$). Correlations were also observed between the excitation factor (3) of the PANSS-5 and factor '2' (affective-negative experiences) of the PRISS, although with values below 0.30. Statistically significant correlations were identified between factor 4 (anxiety/depression) of the PANSS-5 and the three factors of the PRISS, where values ranged from 0.30 to 0.41. The cognitive factor (5) of the PANSS-5 had statistically significant correlations with factor '2' (negative affective) of the PRISS with values ranging from 0.21 to 0.28 (Table 6).

Statistically significant correlations were also found between the WHO-DAS 2.0 and the three factors of the PRISS in each of its characteristics. The highest correlations were observed between the WHO-DAS 2.0 and factor '2' (affective-negative experiences), where correlations from 0.46 to 0.50 were found, followed by factor '3' (excitation), with correlations ranging between 0.26 and 0.30 and, finally, factor '1' (productive experiences) with correlations from 0.21 to 0.24 (Table 6).

TABLE 5 Convergent validity. Pearson correlation coefficients between the PRISS characteristics and the PANSS, PANSS-2, SANS and WHO-DAS 2.0 scores ($N = 162$).

	PRISS	PANSS	PANSS−2		SANS		
PRISS characteristics	**PRISS items**		**Factor 1. diminished expression**	**Factor 2. amotivation**	**Alogia**	**Avolition-apathy**	**WHO-DAS 2.0.**
Presence-frequency	Total score	0.42**					0.42**
	Lack of spontaneity (12)				0.19		
	Motor retardation (20)					0.38**	
	Blunted affect (8), Poor rapport (9), Lack of spontaneity (12), Motor retardation (20)		0.32**				
	Passive social withdrawal (10), Active social avoidance (28)			0.22*			
Worry	Total score	0.38**					0.41**
	Lack of spontaneity (12)				0.14		
	Motor retardation (20)					0.36**	
	Blunted affect (N1), Poor rapport (9), Lack of spontaneity (12), Motor retardation (20)		0.29**				
	Passive social withdrawal (10), Active social avoidance (28)			0.18			
Interference†	Total score	0.38**					0.40**
	Lack of spontaneity (12)				0.17		
	Motor retardation (20)					0.32**	
	Blunted affect (N1), Poor rapport (9), Lack of spontaneity (12), Motor retardation (20)		0.30**				
	Passive social withdrawal (N4), Active social avoidance (28)			0.14			

Note: Interference†, Interference with daily life; PRISS, Patient-Reported Impact of Symptoms in Schizophrenia Scale; PANSS, Positive and Negative Syndrome Scale; PANSS-2, two domains of factor analysis of negative symptoms of the PANSS; SANS, Scale for the Assessment of Negative Symptoms; WHO-DAS 2.0., WHO Disability Assessment Schedule.

* $p < 0.05$.; ** $p < 0.01$.

TABLE 6 Convergent validity. Pearson correlation coefficient between the PRISS factors and its characteristics, the PANSS-5 and the WHO-DAS 2.0 scores ($N = 162$)

		Factors of the PANSS−5					
PRISS	**PRISS**	**1. Negative**	**2. Positive**	**3. Excitation**	**4. Anxiety/ depression**	**5. Cognitive**	**WHO-DAS 2.0.**
Factors	Characteristics						
1. Productive experiences	Presence-Frequency	0.14	0.26**	0.22*	0.34**	0.20*	0.21*
	Worry	0.30**	0.23*	0.14	0.30**	0.14	0.23*
	Interference†	0.20**	0.36**	0.15	0.31**	0.25*	0.24*
2. Affective – negative	Presence-Frequency	0.43**	0.31**	0.27**	0.40**	0.28**	0.50**
	Worry	0.37**	0.32**	0.24*	0.40**	0.26**	0.47**
	Interference†	0.45**	0.30*	0.22*	0.36**	0.21*	0.46**
3. Excitation	Presence-Frequency	0.18	0.17	0.19	0.39**	0.14	0.29**
	Worry	0.14	0.15	0.20*	0.38**	0.09	0.26**
	Interference†	0.22**	0.22*	0.24*	0.41**	0.18	0.30**

Note: Interference†, Interference with daily life; PRISS, Patient-Reported Impact of Symptoms in Schizophrenia Scale; PANSS-5, Positive and Negative Syndrome Scale (Emsley et al., 2003); WHO-DAS 2.0., WHO Disability Assessment Schedule.

* $p < 0.05$.; ** $p < 0.01$.

4 | DISCUSSION

This study presents the development and the psychometric properties of the PRISS, a new instrument to assess the impact of subjective experiences or qualia complementary to objective symptoms in outpatients with schizophrenia. This 28-item scale evaluates four characteristics: presence, frequency, worry and interference in daily life of self-reported experiences in patients with schizophrenia. This measurement of qualia complements and mirrors the clinical evaluation of a set of symptoms commonly assessed in schizophrenia. Hence, the PRISS could fill the gap between self-perceived and observer-rated psychopathology in this condition. A significant advantage of the PRISS in comparison with other scales, such as the Symptom Self-rating Scale for Schizophrenia (4S),[9] is its validation in different community care environments.

The PRISS shows good structural validity, with items clustered into a three-factor structure: (1) productive experiences, (2) affective-negative experiences and (3) excitation. As expected, younger age was associated with the excitation factor including reported excitement, hostility and tension. Younger age at first hospitalization was associated with the productive experiences factor, as previously reported.[34] This could be related to the natural course of the disease, since positive experiences predominate initially but are gradually surpassed by negative experiences. The PRISS showed good test-retest reliability, and very few ICCs showed statistically non-significant values. Disorientation showed low reliability when analysed in isolation. However, the overall reliability of the PRISS factors (factor '1' for presence-frequency, factor '2' for worry and factor '3' for interference with daily life) improved when this item was taken into account, resulting in acceptable reliability. Convergent validity was analysed in relation to the PANSS, SANS and WHO-DAS 2.0, each covering a different dimension of the same entity.[35] As qualia and symptoms are different aspects of mental health status, the convergent analysis with the PANSS and the SANS should produce moderate rather than high levels of concordance. The correlation between the PRISS factors and the PANSS and the SANS was acceptable but not strong. This reinforces the assumption that the PANSS and the PRISS measure complementary aspects in psychopathology—symptoms from the clinician's point of view (PANSS) and qualia from the patient's point of view (PRISS). Another alternative explanation is that the match between some item of the PRISS and its counterpart of the PANSS is not complete. For example, the PRISS delusion item refers to a very specific Schneiderian-type delusion of control, whereas the PANSS covers all delusions. Mass et al. found statistically significant differences between PROs and objective severity indexes in neurology.[36]

Stronger correlations were found between the excitement factor of the PRISS and the WHO-DAS 2.0 in comparison with the correlation found between the PRISS and the PANSS. This finding indicates that qualia may

be closer to the domains of well-being and functioning than their equivalent clinical symptoms. This is relevant as PROs offer a more accurate indicator of quality of care than other standardized quality indicators.[37]

Self-reported measures are appropriate to assess positive[38,39] and prodromal psychotic symptoms,[40,41] although lack of insight in people with schizophrenia could affect the validity of the assessment of symptoms in self-reported measures,[42] even in patients without an acute psychotic episode.

It is important to note that half of the interviewees preferred the PRISS-assisted completion form. Previous studies have found that self-completion and assisted completion produce equivalent scores overall,[43] and their combined use has been tested in chronic conditions[44] and mental illnesses.[45] The availability of interviewer-assisted and unassisted versions of PRISS may be relevant from a clinician perspective, to facilitate completion. In addition, the self-perception of experiences complements the information obtained when recording equivalent observed symptoms.

There are a number of limitations to our study. Men are slightly overrepresented in our sample; however, this situation occurs in the majority of mental health centres concerning patients with severe mental illness in Spain. In addition, the inclusion criteria were limited to adult patients with stable schizophrenia, excluding patients with an acute psychotic episode or other psychotic disorders. This requirement limits generalization. The PRISS was developed and tested only in a Spanish-speaking sample. However, an English version has been made available to facilitate its dissemination and validation in English-speaking samples, in future studies.

It is relevant to mention the current terminological debate between PROMs and patient-reported experience measures or PREMs.[46] While PROMs 'capture how patients function or feel with respect to their health; disease condition and its treatment; or functional status, quality of life, or mental well-being', while PREMs refer to 'how patients feel with respect to their healthcare or illness experience'. This distinction is controversial particularly in mental health, where there is a clear overlap between reported measures of the disease condition and the illness experience. This terminological debate is beyond the scope of this paper, where we used PROM as the generic term for the entire set of patient-reported instruments, including the PRISS.

Our findings suggest that the PRISS is a brief, valid and reliable scale to assess qualia or self-perception of symptoms and their subjective impact on patients with schizophrenia. This questionnaire could provide valuable information for the assessment of outcomes in patients with severe mental illness in routine clinical evaluation. Important next steps include evaluating the utility of the scale and its implementation across different languages, populations, risk groups (e.g., adolescents with at-risk mental states) and in other psychotic disorders.

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CONFLICT OF INTERESTS

The authors declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/acps.13417.

DATA AVAILABILITY STATEMENT

Data supporting the findings of this study and the validated Spanish version of the PRISS scale are available from the corresponding author upon reasonable request.

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