

Miguel A. García-Carretero¹
Laura Moreno-Hierro²
María A. Jordán-Quintero³
María Robles-Martínez⁴
Ana M. Sainz-Otero⁵
José P. Novalbos-Ruiz⁶

Translation and validation of the "personal evaluation of transitions in treatment (PETIT)" scale for people with schizophrenia

¹ CTS-391 Multidisciplinary Group for the progress of Mental Health, Faculty of Nursing and Physiotherapy, University of Cadiz, Spain

² Doctoral Programme, University of Cadiz, Spain

³ Puerta del Mar University Hospital, Cadiz Emergency Services, Spain

⁴ CAS Forum. Institute of Neuropsychiatry and Addictions (INAD). Parc de Salut Mar, Barcelona, Spain

⁵ Department of Nursing and Physiotherapy. Faculty of Nursing and Physiotherapy, University of Cadiz, Spain.

⁶ Department of Biomedicine, Biotechnology and Public Health, School of Medicine, University of Cadiz, Spain.

TRANSLATION AND VALIDATION OF THE "PERSONAL EVALUATION OF TRANSITIONS IN TREATMENT (PETIT)" SCALE FOR SCHIZOPHRENIC POPULATION

ABSTRACT

Aims. To adapt the 'Personal Evaluation of Transitions in Treatment (PETIT)' scale into Spanish and analyse its psychometric properties on schizophrenic population.

Method. 223 patients in outpatient treatment diagnosed with schizophrenia according to DSM-5 criteria participated in the study. A defined variable 'therapeutic compliance', DAI10 and SMAQ were used as a gold standard and the psychometric properties of the scale were analysed at three time points (baseline, 1 month and 6 months).

Results. The scale has very high face (or logical) validity. Exploratory factor analysis showed it would be necessary to eliminate item 7. The reliability of the scale is high (Cronbach's alpha = 0.91), demonstrating good internal consistency. After eliminating item 7, confirmatory factor analysis obtained 5 components that explained 57,76% of the variance. The content of the scale is valid for discriminating between patients of different treatment adherence, response and quality of life. The cut-off point of the 'PETIT' scale in Spanish is set at 24 points for both sexes, with good sensibility to change and very good concordance force over the three time points evaluated.

Conclusions. After eliminating item 7 and using '24' as cut-off point, the 'PETIT' scale was able to detect changes in both adherence and response to treatment as well as the resulting modifications to the quality of life of patients. Its use as a single instrument to measure all of the above makes it advisable for use in clinical practice, as the evaluation methods it requires are relatively simple and quick to perform.

Keywords. Schizophrenia; adherence; PETIT; Psychometrics/methods*; quality of life.

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TRADUCCIÓN Y VALIDACIÓN DE LA ESCALA "PERSONAL EVALUATION OF TRANSITIONS IN TREATMENT (PETIT)" PARA POBLACIÓN CON ESQUIZOFRENIA

RESUMEN

Objetivo. Adaptar al español la escala Personal Evaluation of Transitions in Treatment (PETIT) y analizar sus propiedades psicométricas en población con esquizofrenia.

Metodología. Participaron 223 pacientes en tratamiento ambulatorio con diagnóstico de esquizofrenia según criterios DSM-5. Se utilizaron como gold estándar la variable cumplimiento terapéutico, DAI10 y SMAQ y se analizaron las propiedades psicométricas de la escala en tres momentos (basal, al mes y 6 meses).

Resultados. La validez de apariencia (lógica) de la escala es muy elevada. En el análisis factorial exploratorio identificamos que sería necesario eliminar el ítem-7. La fiabilidad de la escala es alta con un alfa-Cronbach de 0,91 demostrando buena consistencia interna. El análisis factorial

Correspondence:

Ana María Sainz Otero,
Department of Nursing and Physiotherapy,
Faculty of Nursing and Physiotherapy,
University of Cadiz
Avda Ana de Viya nº 52. 11009, Cadiz
Email: ana.sainz@uca.es

confirmatorio tras eliminar el ítem-7 obtiene 5 componentes que explican el 57,76% de la varianza. El contenido de la escala es válido para discriminar pacientes con diferente adherencia, respuesta al tratamiento y calidad de vida. El punto de corte de la escala PETIT en español se establece en 24 puntos para ambos sexos; presentando una buena sensibilidad al cambio, y una fuerza de concordancia muy buena para los tres momentos evaluados.

Conclusiones. La escala PETIT tras eliminar el ítem-7 y utilizando 24 como punto de corte permite detectar cambios en la adherencia al tratamiento, su respuesta y las modificaciones resultantes en la calidad de vida de los pacientes. Su uso como único instrumento que mide todo lo anterior lo hace recomendable en la práctica clínica ya que esta precisa de métodos de evaluación sencillos que no consuman grandes esfuerzos o tiempo.

Palabras clave. Esquizofrenia; adherencia; PETIT; Psicometría; calidad de vida.

INTRODUCTION

Schizophrenia is a serious mental disorder affecting more than 21 million people in the world, around 1% of the general population¹. Its treatment should be aimed at eliminating symptoms after they appear, preventing new ones and rehabilitating sufferers². Therefore, pharmacological treatment, adjuvant therapies, psychosocial work and education are essential as part of rehabilitation, with adequate adherence to treatment also being fundamental^{2,3}.

The beliefs of these patients and attitudes towards their condition and treatment are better predictors of treatment adherence and quality of life than any other sociodemographic or clinical variable⁴⁻⁶; therefore, many questionnaires assessing adherence focus on analysing these beliefs and attitudes. There are currently a large number of assessment scales for therapeutic compliance and quality of life, although there is no single reference method; so several have to be used to compensate for the deficiencies that each has⁷⁻⁹.

PETIT¹⁰ evaluates the subjective responses of individuals to antipsychotic medications, adherence to treatment and changes in quality of life; although the psychometric properties of this scale have not been studied in the Spanish population.

The objective of this study was to adapt the Personal Evaluation of Transitions in Treatment (PETIT) scale into Spanish and analyse its psychometric properties for application in the Spanish population with schizophrenia.

METHODOLOGY

The study was carried out in two phases: Firstly, the PETIT scale was translated, following the translation and reverse translation methodology proposed by Guillermin *et al.*¹¹. In the second phase, the PETIT scale was validated in 223 patients diagnosed with schizophrenia who attended the consultation from March 2018 to June 2019, in 5 types of mental health centres: 2 mental health units, 1 district, 1 community, 1 rehabilitation unit and FAISEM supervised flats, all of which were in municipalities in Cádiz province.

The Carretero-Dios and Pérez criteria¹² were followed for the sample size. It proposed samples of 5-10 individuals per item in the implementation and review of instrument studies; providing a sample of 225 subjects (7.5 x 30 items). These subjects were selected by consecutive non-probabilistic random sampling in order of appointment to the nursing consultation. Initially, 228 patients participated, but 5 questionnaires were invalidated for not completing the re-test, the rest of the questionnaires or for abandoning the study: this left a sample of 223 patients. All participants signed a written consent form and the study was approved by the Cádiz Ethics Committee, in accordance with Good Clinical Practice and the Helsinki Declaration.

Inclusion criteria: (1) Primary diagnosis of schizophrenia according to DSM-5. (2) Initial diagnosis of schizophrenia made at least 1 year before the study start. (3) Patient without mental retardation, acquired brain injury, any other severe mental disorder or severe sensory limitations that prevent testing. (4) Age 18-65 years inclusive.

Exclusion criteria: Patients complying with the inclusion criteria, but whose participation could affect their treatment, in the opinion of the professionals who attended them: either due to being in the acute stage of the condition or for having symptoms suggestive of the onset of psychopathological decompensation.

The most relevant sociodemographic and clinical features for this type of study were noted (Table 1). For the "Therapeutic compliance" variable, the nurse recorded if the patients had attended scheduled appointments during the previous 6 months and if they had taken the medication, using a compliant/non-compliant dichotomous response (as an indirect method based on the clinical interview). Directly observed therapy (DOT) was also used for patients undergoing injection or mixed treatments. Patients were considered compliant if they attended at least 80% of the scheduled consultations and there was evidence of injection treatment administration (DOT) and/or the patient showed strict oral treatment follow-up.

Psychopathology was evaluated using the Positive and Negative Syndrome Scale for Schizophrenia (PANSS)¹³, as validated in Spanish¹⁴. Given its complexity, researchers were trained in its use.

The Personal Evaluation of Transitions in Treatment (PETIT) scale¹⁰ assessed subjective changes perceived during the course of antipsychotic drug therapy for schizophrenia, especially the subjective responses of individuals to

medications, adherence to treatment and changes in quality of life. It consists of a self-administered questionnaire of 30 questions (or items) with 3 possible responses (often/sometimes/never). Each item is assigned a rating of 0, 1 or 2; where 0 indicates a negative change in health-related quality of life (HRQL) and 2 indicates a positive change (better HRQL). The total score ranges from 0-60 points, with higher scores reflecting a better HRQL¹⁵.

Table 1		Sociodemographic data			
VARIABLES	MEN, n=145	WOMEN, n=78	ALL, N=223	P	
Age	47.4 (10)	46.7 (10.5)	47.2 (10.2)		
Marital status			0.000	0.000	
Single	89	60.3	78.9		
Married/common-law partner	5.5	19.2	10.3		
Divorced/separated	2.8	16.7	7.6		
Widowed	2.8	3.8	3.1		
Living conditions				0.018	
With family	45.5	64.1	52		
Alone	15.9	15.4	15.7		
FAISEM facility	28.6	20.5	32.2		
Education				0.009	
No qualifications	25.5	28.2	26.5		
Secondary education (ESO)	60	44.9	54.7		
Higher or Vocational	9	24.4	14.3		
University	5.5	2.6	4.5		
Employment					
Never worked	72.4	74.4	73.1		
Unemployed	17.9	16.7	17.5		
Paid contract	2.1	2.6	2.2		
Occupational workshops	7.6	6.4	7.2		
Age onset of disease	20.1 (4.4)	23 (5.3)	21.1 (4.9)		
Evolution of disease	27.3 (10.1)	23.6 (10.7)	26 (10.4)		
Treatment type					
Oral	14.5	10.3	13		
Injections	27.6	34.6	30		
Mixed (both)	57.9	55.1	57		
Therapeutic compliance				0.002	
Adherent	69.7	48.7	62.3		
Not adherent	30.3	51.3	37.7		
Family history of disease					
None	39.3	55.1	44.8		
1st degree relatives	42.1	28.2	37.2		
2nd degree relatives	7.6	6.4	7.2		
1st and 2nd degree relatives	11	10.3	10.8		
Other pathologies					
None	47.6	50	48.4		
Diabetes Mellitus	14.5	21.8	17		
High BP	9	5.1	7.6		
Endocrinological	9.7	14.1	11.2		
Drug use in last 12 months				0.008	
Tobacco	82.8	70.5	78.5		
Alcohol	21.4	12.8	18.4		
All recreational drugs	31.7	15.4	26		
Cocaine	20.7	9	16.6		
Hashish	9	6.4	8.1		
Marijuana	2.1	-	1.3		

Standard deviation in brackets

The Simplified Medication Adherence Questionnaire (SMAQ)¹⁶ consists of 6 items. Patients were considered not adherent if they answered one or more of the qualitative questions as follows: (1) yes; (2) no; (3) yes; (4) yes; (5) C, D or E; (6) 'more than 2 days'.

The Drug Attitude Inventory (DAI-10)¹⁷, validated in Spain¹⁸, consists of 10 items. Questions 1, 3, 4, 7, 9 and 10 are scored +1 if the answer is 'true' and -1 if false; questions 2, 5, 6 and 8 are scored inversely. A positive total score means a positive subjective response and good adherence, while a negative total score means a negative subjective response and poor adherence.

As there is no simple, reliable 'gold standard' to measure adherence¹⁹⁻²¹ in these patients, the "therapeutic compliance" variable (according to the aforementioned criteria) and the DAI-10 and SMAQ questionnaires were used in combination as a reference standard to compare with the PETIT scale.

A patient was classified as adherent or not adherent according to the following criteria:

(1) Adherent – If patients classified as adherent in both questionnaires (DAI-10 and SMAQ); or if patients classified as adherent in one of these questionnaires as well as being classified as adherent for the "therapeutic compliance" variable.

(2) Not adherent – Any other combination; e.g. classifying as compliant in the "therapeutic compliance" variable was not considered sufficient if the patient was not also adherent in both the DAI-10 and SMAQ questionnaires.

All patients completed the PETIT on two occasions: at the baseline visit (R_0) and after 1 or 1.5 months (R_1), at the next consultation visit. At baseline, sociodemographic information and clinical data were compiled, along with the clinical history, with the PANSS being completed after the interview. The patient then completed the PETIT. At the second visit, the PANSS was completed and the patient completed the PETIT, DAI-10 and SMAQ questionnaires.

At 6 months (R_2), 1 from every 5 patients (total of 45) completed the PETIT and the PANSS to assess their sensitivity to change.

The items were analysed individually for the feasibility evaluation, and the non-response percentages obtained. The ceiling and floor effect and the time taken to complete were also analysed.

Reliability was measured by internal consistency, using Cronbach's alpha coefficient. The test-retest method was

also carried out. The intraclass correlation coefficient (ICC) was also calculated, with a value ≥ 0.80 considered as satisfactory.

Spearman's rank correlation coefficient was also performed for content validity, to see how the different items correlated. Construct validity was analysed by confirmatory factor analysis of principal components with varimax rotation.

The criteria and diagnostic validity of the questionnaire were first assessed by comparing the mean scores in two groups of patients with significant PETIT score differences. Subsequently, a comparison of the diagnoses provided by the PETIT scores with the reference standard was carried out.

To determine the test cut-off point, the ROC curve and the Youden index (J) for the different 'reference standard' criteria were obtained. The sensitivity to change of the PETIT scale was analysed. PANSS made it possible to observe changes in the patient's condition and it was analysed whether they corresponded to those obtained in the PETIT at R_0 , R_1 and R_2 periods. First, the percentage agreement was analysed, then the kappa agreement was calculated for the periods $R_0 - R_1$, $R_1 - R_2$ and $R_0 - R_2$.

RESULTS

There were 223 patients (65% male) in the study, with a mean age of 47.2 years (SD 10.2) and an age range of 19-65 years.

There were 78.9% single and 10.3% married or with common-law partners. Around half (52%) were living with relatives and 32.2% in FAISEM accommodation. For educational level, 54.7% had reached obligatory secondary school level (ESO), 26.5% had no qualifications and 4.5% had attended university. Most (73.1%) had never worked and 17.5% were unemployed.

The mean age of onset of the condition was 21.1 years (SD 4.9), and was lower in men (20.1 vs 23 years in women). Mean disease evolution was 26 years (SD 10.4), with 27.3 years in men and 23.6 years in women. Mixed treatment was given to 57% and injection treatment to 30%, while therapeutic compliance was 62.3%. The family history of psychiatric pathology showed 44.8% had no such history and 37.2% had first degree relatives affected. Around half (48.4%) had no other pathologies, 17% had diabetes mellitus, 11.2% endocrine disorders and 7.6% high BP.

Drug use over the previous 12 months showed 78.5% had used tobacco, 18.4% alcohol and 26% recreational

drugs, with the most commonly used being cocaine (16.6%) and hashish (8,1%).

The psychopathological status of the sample using the PANSS scale had an initial score of 23.8 (SD 9.9) for the positive scale, 24.8 (SD 9.2) for the negative scale, 48.8 (SD 14.6) for general psychopathology and a total score of 97.3 (SD 30.2).

For feasibility, of the 228 respondents, 5 questionnaires (2.19%) were invalidated, due to abandonment, not completing the retest or the rest of the questionnaires; leaving 223 patients (97.8%). Items were analysed individually, with zero non-response being obtained.

The ceiling and floor effect for the percentage of subjects with the highest and lowest possible PETIT score was analysed: the lowest score was 11 points from 6 respondents (2.7%) and the highest score was 54 from 4 respondents (1.8%). No subject reached the maximum (60 points) or minimum (0 points) scores.

The completion time was adequate according to the recommendations (3-5 minutes) of the authors of the original version. The mean time taken was 3'36" (SD 35.815"; range 3'36" - 4'48"); only 2 people (0.45%) were outside this time range.

For reliability with this population of 223 subjects, the different items enquiring about different elements in the two questionnaire domains showed very high internal consistency values (Cronbach's alpha = 0.913). Removing items 7 and 22 from Domain 1 and item 26 from Domain 2 gave even higher internal consistency values (Cronbach's alpha = 0.924).

When performing the test-retest (Table 2), similar central tendency (mean, median and mode) values were observed, as well as some positive skew, with values or responses extending to the right, and negative kurtosis, with lower tails.

There was a strong, statistically significant, direct correlation between the PETIT scale at R_0 and R_1 ($r=0.928$, $p<0.05$). After checking the correlation of the responses at the time points R_0 and R_1 for each item, very high correlation is seen, so the test can be said to be very stable before and after (Table 3).

Face validity made it possible to assess the clarity and understanding of the instrument without ambiguity, with understanding assessed at 9.86 and no elements for improvement found. No comprehension difficulties were detected and the translated items were answered affirmatively by all professionals and patients.

Spearman's rank correlation for content validity was performed for the different items. Taking the correlation coefficients for each item with the subdomains, the instrument was divided into 2 domains with 4 subdomains: Domain 1 "Psychosocial functioning" (items 1-24) was divided into the 4 subdomains: "Social functioning" (items 4, 7, 11 and 19), "Activity" (items 3, 5, 12, 14, 16, 21 and 23), "Cognition" (items 1, 2, 6, 9, 13, 15 and 20) and "Dysphoria" (items 8, 10, 17, 18, 22 and 24). Domain 2 was "Adherence and feelings towards the medication" (items 25-30).

Exploratory factor analysis (EFA) showed first that the anti-image correlation of item 7 was 0.286, while it was 0.7-0.8 for the rest of the items. According to the principal components method, it considers 8 factors and explains 67.69% of the variance. Furthermore, the factorial loads of items 3, 14 and 12 had values below 0.5 with item 7 having the lowest (0.167). Thus, it would be advisable to consider removing item 7.

Following the EFA results, and after deciding to remove item 7, confirmatory factor analysis (CFA) of the main components with varimax rotation was performed. It was found that 7 factors explained 65.65% of the variance. The anti-image correlation was good with values of 0.7-0.8 for all items (Table 4).

Table 2	PETIT scale test and retest results								
	N	Mean	Standard Deviation	Minimum	Maximum	Skew		Kurtosis	
						Value	Standard error	Value	Standard error
PETIT	223	28.74	11.173	11	51	0.033	0.163	-1.080	0.324
REPETIT	223	28.95	11.448	11	54	0.083	0.163	-1.041	0.324

Table 3 PETIT scale item correlation with domains and subdomains					
ITEM	Domain 1				Domain 2
	Subdomain 1.1	Subdomain 1.2	Subdomain 1.3	Subdomain 1.4	
1	0.267** 0.000	0.257** 0.000	0.511** 0.000	0.212** 0.001	0.215** 0.001
2	0.070 0.300	0.192** 0.004	0.408** 0.000	0.094 0.160	0.066 0.327
3	0.417** 0.000	0.622** 0.000	0.377** 0.000	0.462** 0.000	0.387** 0.000
4	0.611** 0.000	0.298** 0.000	0.308** 0.000	0.260** 0.000	0.242** 0.000
5	0.419** 0.000	0.561** 0.000	0.417** 0.000	0.467** 0.000	0.386** 0.000
6	0.483** 0.000	0.474** 0.000	0.559** 0.000	0.372** 0.000	0.241** 0.000
7	0.322** 0.000	0.014 0.836	0.025 0.705	-0.067 0.320	-0.048 0.477
9	0.543** 0.000	0.476** 0.000	0.740** 0.000	0.459** 0.000	0.471** 0.000
10	0.419** 0.000	0.559** 0.000	0.561** 0.000	0.793** 0.000	0.549** 0.000
11	0.697** 0.000	0.468** 0.000	0.488** 0.000	0.486** 0.000	0.567** 0.000
12	0.328** 0.000	0.634** 0.000	0.360** 0.000	0.420** 0.000	0.458** 0.000
13	0.471** 0.000	0.514** 0.000	0.679** 0.000	0.451** 0.000	0.339** 0.000
14	0.371** 0.000	0.718** 0.000	0.459** 0.000	0.537** 0.000	0.511** 0.000
15	0.391** 0.000	0.495** 0.000	0.718** 0.000	0.388** 0.000	0.540** 0.000
16	0.537** 0.000	0.714** 0.000	0.564** 0.000	0.475** 0.000	0.392** 0.000
17	0.450** 0.000	0.505** 0.000	0.500** 0.000	0.758** 0.000	0.421** 0.000
18	0.361** 0.000	0.396** 0.000	0.321** 0.000	0.704** 0.000	0.367** 0.000
19	0.796** 0.000	0.629** 0.000	0.628** 0.000	0.507** 0.000	0.440 0.000
20	0.539** 0.000	0.560** 0.000	0.753** 0.000	0.547** 0.000	0.451** 0.000
21	0.433** 0.000	0.631** 0.000	0.439** 0.000	0.312** 0.000	0.323** 0.000
22	-0.082 0.222	0.140* 0.037	0.071 0.292	0.409** 0.000	0.195** 0.003
23	0.152* 0.023	0.469** 0.000	0.282** 0.000	0.394** 0.000	0.384** 0.000
24	0.458** 0.000	0.452** 0.000	0.437** 0.000	0.545** 0.000	0.208** 0.002
25	0.456** 0.000	0.578** 0.000	0.484** 0.000	0.522** 0.000	0.775** 0.000
26	0.057 0.394	0.191** 0.004	0.040 0.550	0.312** 0.000	0.494** 0.000
27	0.326** 0.000	0.419** 0.000	0.218** 0.001	0.409** 0.000	0.753** 0.000
28	0.591** 0.000	0.560** 0.000	0.558** 0.000	0.504** 0.000	0.692** 0.000
29	0.494** 0.000	0.573** 0.000	0.509** 0.000	0.504** 0.000	0.840** 0.000
30	0.401** 0.000	0.550** 0.000	0.441** 0.000	0.514** 0.000	0.762** 0.000

** Correlation is significant at the 0.01 level (2 tails).

* Correlation is significant at the 0.05 level (2 tails).

Ítems	Components						
	1	2	3	4	5	6	7
29	.773	.071	.181	.320	.005	.100	.156
30	.739	.230	.104	.018	.245	-.091	-.015
28	.713	.215	.252	-.178	.219	.129	.248
8	.653	.196	.129	.055	.311	.166	-.051
25	.619	.158	.227	.389	.062	.038	.022
11	.618	.121	.252	-.261	.319	-.039	.259
27	.564	.062	-.121	.468	.068	-.330	.175
24	.088	.748	.141	-.099	.162	.157	.177
21	.279	.726	.165	-.147	.006	-.002	.070
16	.173	.709	.309	.132	.143	-.038	.047
6	.119	.565	.083	.046	.113	.281	.336
14	.431	.432	-.021	.348	.183	.244	-.102
12	.149	.419	.255	.365	.156	-.150	-.056
13	.016	.187	.683	.309	.276	.102	.049
9	.455	.216	.633	.054	-.078	.106	.200
20	.201	.192	.579	.260	.368	.126	.045
15	.544	.251	.560	-.017	-.093	.105	-.119
1	.154	.124	.546	-.260	.201	-.128	.037
19	.223	.356	.478	.119	.324	.143	.252
22	-.094	-.142	-.019	.766	.142	.055	.052
23	.163	.099	.173	.756	-.019	.073	-.034
26	.208	-.064	-.018	.519	.130	-.447	-.139
17	.213	.116	.343	.083	.697	-.046	.077
18	.076	.033	.056	.431	.685	.066	.309
10	.482	.175	.310	.081	.612	.033	-.234
3	.219	.431	.069	-.063	.588	-.110	-.004
2	.112	.084	.090	.037	-.031	.823	-.061
5	.316	.188	-.022	.131	.324	.443	.402
4	.110	.228	.128	-.036	.051	-.055	.827

Items 5, 12, 14 and 19 had values less than 0.5, with the rest of the items having higher values. Thus, it would be advisable to remove them. The following table shows how the 7 factors are distributed.

The mean scores in 3 groups of patients with significant differences in the PETIT scores were compared

for criteria and diagnostic validity. Significantly higher or lower scores were found on the PETIT, according to the reference standard classification of adherent or not adherent, respectively. Thus, the PETIT content is valid for discriminating groups of individuals in different situations (Table 5).

The best balance between sensitivity and specificity for the PETIT was found for a score of 24 points for both sexes (Sensitivity S)=97% Specificity (SP)=88% for males vs S=95% SP=90% in females).

Finally, Cohen's kappa coefficient, which adjusts for the effects of chance when considering concordance, was greater than 0.8 for the periods R_0-R_1 , R_1-R_2 and R_0-R_2 which is indicative of very good agreement for the three periods evaluated (Table 6).

		PETIT		GOLD ADHERENCE		DAI 10	
		Mean	SD**	Yes	No	Yes	No
GROUP 1 11 a 21 points	Total	15.34	3.117	4.2	95.8	-	100
	Hombre	15.05	3.220	2.6	97.4	-	100
	Mujer	15.69	2.999	6.3	93.8	-	100
GROUP 2 22 a 34 points	Total	29.23	3.772	82.5	17.5	80.8	19.2
	Hombre	29.79	3.524	89.5	10.5	84.3	15.7
	Mujer	27.83	4.075	65.2	34.8	72.7	27.3
GROUP 3 35 a 51 points	Total	41.43*	4.663	95.8	4.2	94.8	5.2
	Hombre	41.78*	4.602	98	2	96.3	3.7
	Mujer	40.70*	4.809	91.3	8.7	91.3	8.7

NOTE.

Group 1: N Total =71; Men (n=39); Women (n=32).

Group 2: N Total =80; Men (n=57); Women (n=23).

Group 3: N Total =72; Men (n=49); Women (n=23).

* Kruskal-Wallis test for independent samples (Sig. 0,000).

**SD: Standard deviation

Kappa	Valid cases	PETIT	k	Asymptotic standard error ^a	Approx S ^b	Approx Sig.
Measure of	223	R_0 y R_1	0.903	0.030	13.478	0.000
	45	R_0 y R_1	0.955	0.045	6.411	0.000
	45	R_1 y R_2	0.908	0.064	6.115	0.000
	45	R_0 y R_2	0.863	0.076	5.844	0.000

Note.

a. Null hypothesis is not assumed.

b. Use of asymptotic standard error, assuming null hypothesis.

N= 223 (Men=145, Women=78).

N= 45 (Men=26, Women=19).

DISCUSSION

The sociodemographic features are very similar to other studies carried out in patients with schizophrenia, regarding mean age, gender distribution, marital status, domestic cohabitants, educational level and occupation¹⁹⁻²⁶.

The mean PETIT score was 28.7 (SD 11.2) at baseline and 28.9 (SD 11.4) at the second visit. These values are similar to those indicated in 3 studies carried out in the United States²⁷⁻²⁹, but significantly lower than those found in other studies^{15,19,30}. For the latter studies, the difference in mean score may be due to the fact that the effectiveness of antipsychotic drugs was evaluated by analysing the PETIT scale results after a 6-month follow-up; thus, these patients were adherent and gave higher scores; while the intention with this scale is to find out if their adherence and quality of life improve after taking one drug or another. Comparing these mean scores with those from our study for the adherents group, they are similar: being 35.7 (SD 7.3) and 36.3 (SD 7.3) for the R₀ and R₁ periods, respectively.

The completion time was found to be adequate, according to the original version of the Voruganti et al recommendations¹⁰. According to these, the PETIT can be completed in about 3-5 minutes, and the average completion time was 3'36", with only 2 people who did not meet this time interval.

The reliability results showed the PETIT has good internal consistency (Cronbach's alpha=0.91), which means it is a useful and reliable tool to detect possible adherence problems in the treatment of patients with schizophrenia. Removing items 7 and 22 in Domain 1 and item 26 from Domain 2 gave higher internal consistency values (Cronbach's alpha=0.92). These data coincide with those in the original version of Voruganti et al¹⁰ in its original version, without there being other subsequent studies with which to make a comparison.

There was also a strong, significant and direct correlation between the PETIT scale at R₀ and R₁ ($r=0.928$, $p<0.05$), indicating it is very stable both before and after.

For the content validity of the PETIT, taking into account the correlation coefficients of each of the items with the subdomains, it was observed that the instrument is divided into 2 domains with 4 subdomains. This division coincides with that of the original instrument design author¹⁰ and with that indicated in a 2014 study by Awad et al¹⁵. There is a "Psychosocial functioning" domain (items 1-21) divided into 4 subdomains ("Social functioning" items 4, 7, 11 and 19; "Activity" items 3, 5, 12, 14, 16, 21 and 23; "Cognition", items 1, 2, 6, 9, 13, 15 and 20; and "Dysphoria" items 8, 10,

17, 18, 22 and 24) and an "Adherence and feelings towards medication" domain (items 25-30).

EFA found that item 7 ("I am unable to trust people") needed to be removed; and that 8 main components were determined that explain 67.69% of the variance. However, the same component structure was not reflected in the original¹⁰, although the values used to decide this are unknown.

After eliminating item 7, CFA showed 5 components were determined that explain 57.76% of the variance. Although this coincides with the original 5-component division indicated by Voruganti et al¹⁰, it did not have the same component structure. Also, items 5, 12, 14 and 19 gave values below 0.5, with the rest of the items having higher values. In view of all the aforementioned results, their elimination would be advisable.

Regarding criteria and diagnostic validity, following the sensitivity and specificity PETIT results (S=96% and E=88%), as well as those according to gender, and after analysing the ROC curves, it was found not to be necessary to establish different cut-off points for men and women, with a single cut-off point of 24 points being sufficient. According to Voruganti et al¹⁰, the original authors of the instrument, the total PETIT scores were significantly related to the pattern of treatment adherence (odds ratio 5.9, chi-square 47.5, $p<0.0001$). For example, subjects whose total scores were below the median were almost 6 times more likely not to comply with their treatment, compared to those who obtained high scores with the PETIT; hence the importance of a cut-off point. However, neither in their validation publication¹⁰, nor in a subsequent 2014 publication by Awad et al¹⁵, do they indicate cut-off points or data above the median; although it does indicate that higher scores reflect better HRQL.

Finally, the PETIT scale was shown to be sensitive to change for the R₀, R₁ and R₂ periods when compared with the PANSS questionnaire. Thus, when the PANSS score increases (when the symptomatology increases are positive, negative or general) the score on the PETIT decreases (indicating a negative change, or worse HRQL) and vice versa; as well as, when there is no change in the score in one instrument, none was observed in the other.

Caqueo-Urizar et al³¹ indicate that disorder severity has a significant association in medication adherence. For example, if adequate adherence is maintained, relapses are reduced, a better symptomatic course is obtained and social interaction improves³²⁻³³. According to Morken et al³⁴, patients with inadequate adherence have around 10 times the risk of relapse and 4 times the risk of hospitalisation. Numerous studies provide evidence of the negative impact

of a lack of pharmacological adherence on the severity of the disease, leading to relapses and readmissions^{32,35-37}. This makes our results of even more interest, as the PETIT was sensitive to the change for 91.9% ($R_0 - R_1$) and 91.1% (entre $R_1 - R_2$) of the sample.

Although causality cannot be shown, it seems that patients with worse symptoms have less adherence; however, this in itself may result in temporary or permanent discontinuation of treatment and lead, therefore, to patient relapse (greater severity).

Most of these studies have described significant associations between clinical symptoms, mainly the severity of negative symptoms and the quality of life^{23,38-40}. Therefore, symptoms would also be a relevant factor in the quality of life.

However, some patients with schizophrenia do not respond completely to treatment and continue to have positive or negative symptoms. According to Starling and Feijo⁴¹, among the causes of this incomplete recovery are poor adherence to treatment, perhaps due to a lack of knowledge of the disease and concerns about side effects, weight gain or extrapyramidal symptoms.

Various studies have used the PETIT together with the PANSS to detect improvements in treatment, therapy or changes in their quality of life^{8,10,15,27-30,42-43}. Other studies use PANSS to assess a therapy, risk of hospitalisation or changes in quality of life⁴⁴⁻⁴⁷.

A limitation of the study is that the data were collected from stable patients who were not in the acute stage of the disease, which may imply some selection bias and the possibility of including patients with better adherence. This potential bias would affect patients with oral treatment more, as adherence was determined by indirect methods (which have more scope for error). Another possible limitation is for the adherence reported by the patient to be influenced by different factors such as potential cognitive deficits or memory bias.

Finally, Starling et al⁴¹ indicated the importance of performing active follow-up after recovery from any episode, to reduce the risk of relapse, including preparing a monitoring plan to catch early warning signs and to be aware of the actual status of antipsychotic medication adherence. Taking this into account, and in view of the study results obtained, it means that the PETIT is a good instrument to detect such changes in patients and to evaluate their adherence to treatment or any modifications in it. Therefore, better adherence can lead to greater treatment efficacy, reducing symptoms and the implications that these entail, such as relapse and hospitalisation⁴⁸⁻⁵².

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CONFLICTS OF INTEREST

The authors declare they have no conflicts of interest related to the article.

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Anex 1

Personal Evaluation of Transitions in Treatment (PETIT), Spanish version

- | | |
|---|--|
| 1. Mi mente está ágil y clara. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 2. Estoy preocupado con lo que le está pasando a mi salud. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 3. Me siento apagado y lento. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 4. Creo que la gente se siente cómoda a mi alrededor. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 5. Me siento muy cansado para hacer las cosas que debería. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 6. Me resulta difícil tener nuevas ideas. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 7. Estoy satisfecho con mi vida. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 8. Soy capaz de concentrarme leyendo o viendo la televisión. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 9. Soy infeliz. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 10. Tengo familia o amigos que me entienden de verdad. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 11. Mi libido sexual es baja. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 12. Soy capaz de comunicarme mejor con la gente. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 13. Las labores como limpiar, lavar o hacer la compra son demasiado para mí. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 14. Soy capaz de recordar cosas fácilmente. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 15. Me siento preparado para trabajar bien como voluntario o por un salario. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 16. Me siento bien conmigo mismo. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 17. Mi futuro es pesimista. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 18. Evito conocer gente nueva. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 19. Me siento raro y extraño. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 20. Puedo manejar los problemas de la vida cotidiana. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 21. Me disgusta mi aspecto. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 22. No duermo bien. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 23. Soy capaz de hacer cosas tan bien como el resto de la gente. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 24. Olvido tomar mi medicación. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 25. Mi medicación me ayuda. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 26. Me disgusta mi medicación actual. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 27. Amigos y familia creen que mi medicación actual es buena para mí. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 28. Tomar medicación es desagradable. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |
| 29. Creo que las cosas buenas sobre tomar medicación compensan las cosas malas. | <input type="radio"/> A Menudo <input type="radio"/> A veces <input type="radio"/> Nunca |

The PETIT Scale, developed by Voruganti and Awad (2002), assesses subjective changes perceived during the course of antipsychotic drug therapy for schizophrenia, specifically assessing individuals' subjective answers to medication, adherence to treatment, and changes in quality of life.

It is a self-administered questionnaire, with 3 possible answers ("often", "sometimes" or "never"). Each item is assigned a score of 0, 1 or 2, where 0 indicates a negative change (i.e., worse health-related quality of life [HRQoL]) and 2 indicates a positive change (i.e., better HRQoL). The total score ranges from 0 to 58 points.

In the Spanish version, which consists of 29 items, a cut-off point of 24 points is established for both sexes (García-Carretero *et al.*, 2022).