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Validation of the semi-structured interview, the FACE Risk Profile, in people with Serious Mental Illness

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ABSTRACT

Introduction. People with Serious Mental Illness (SMI) could present risk behaviour that may lead to relapses. There are few instruments validated in our context to assess risk factors, but none takes into account several factors at the same time, and is specific for the risk of relapse. The objective of this work is to validate the Functional Analysis of Care Environments (FACE) Risk Profile into Spanish for people with SMI.

Methods. The sample consisted of 69 participants with SMI. The first evaluation was administered using a sociode-mographic questionnaire, the FACE Risk Profile and psychometric instruments for clinical and psychosocial assessment. For the second evaluation, the FACE Risk Profile was re-administered.

Results. The FACE Risk Profile shows adequate internal consistency, good test-retest reliability and adequate concurrent and discriminant validity. The inter-rater agreement is very good.

Conclusions. The FACE Risk Profile is a useful and valid instrument for risk assessment in people with SMI.

Keywords. severe mental illness, risk behaviours, relapse, FACE Risk Profile

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VALIDACIÓN DE LA ENTREVISTA SEMIESTRUCTURADA FACE RISK PROFILE EN PERSONAS CON TRASTORNO MENTAL GRAVE

RESUMEN

Introducción. Las personas con Trastorno Mental Grave (TMG) pueden presentar conductas de riesgo que pueden dar lugar a recaídas. Hay pocos instrumentos validados en nuestro contexto para valorar factores de riesgo y ninguno que tenga en cuenta diversos factores al mismo tiempo y sea específico para valorar el riesgo de recaída. El objetivo de este trabajo es la validación en español de la Functional Analysis of Care Environments o FACE Risk Profile en personas con TMG.

Metodología. La muestra se compone de 69 participantes con TMG. En la primera evaluación se administró un cuestionario sociodemográfico, la FACE Risk Profile e instrumentos psicométricos de valoración clínica y psicosocial. En una segunda evaluación, se volvió a administrar la FACE Risk Profile.

Resultados. La FACE Risk Profile presenta una consistencia interna adecuada, buena fiabilidad test-retest y adecuada validez concurrente y discriminante. El acuerdo interevaluadores es muy bueno.

Conclusiones. La FACE Risk Profile en un instrumento útil y válido para la valoración del riesgo en personas con TMG.

Palabras clave. Trastorno mental grave, conductas de riesgo, recaída, FACE Risk Profile.

INTRODUCTION

Risk in mental health is defined as the probability that an event with harmful results for a person occurs.¹ Risk behaviours such as suicide, self-harm, violence and abuse by third parties are significant in people with Severe Mental Illness (SMI).¹ People with schizophrenia and other psychotic disorders have a high prevalence of suicide² and suicide has been considered the main cause of premature death.³ It is estimated that 13.5% of people with schizophrenia commit suicide³ and have a 12 times higher risk of dying following autolytic behaviour than the general population.⁴.⁵ In addition, the population with SMI exhibits other risk behaviours such as self-harm,⁴ self-neglect,² poor adherence to treatment⁴ and heteroaggressions.⁵.¹10,111

The risk behaviours that people with SMI present have important repercussions on their physical and emotional wellbeing and their adaptation, therefore clinical evaluation of these behaviours is necessary. 12,13,14, 15 The objective of clinical evaluation is to identify vulnerable people and develop strategies for prevention or risk management. For an adequate clinical evaluation, it is essential to have tools that provide a systematic and comprehensive assessment of risk behaviours and the factors contributing to their maintenance or exacerbation. One of the strategies to assess risk in people with SMI in our context is the establishment of cut-off scores for items on the Calgary Depression Scale 16,17 or the Positive and Negative Syndrome Scale.¹⁸ There are also risk assessment instruments adapted and validated into Spanish, such as the Plutchik Suicidal Risk Scale, 19,20 the Plutchik Impulsivity Scale^{19,21} and the Plutchik Violence Risk Scale.^{22,23} However, their use has not been adapted and validated in the population with SMI, which is a clear limitation. Among the risk assessment instruments adapted and validated for people with SMI are the Overt Aggression Scale^{24,25} and the Psychosocial Risk Scale.^{26,27} All these scales measure specific types of risk and do not have a systematic and comprehensive approach.

The FACE is one of the instruments for systematic and comprehensive risk assessment is the Functional Analysis of Care Environments (FACE) Risk Profile AMH v.6.²⁸ For the validation of the FACE Risk Profile,¹⁵ most of the data was compiled in the context of a national project based at the British Psychological Society's Centre for Outcomes Research and Effectiveness at University College London, funded by the Department of Health's National Centre for Health Outcomes Development. This involved collecting data on a sample of users from 25 mental health services in both hospital and community settings in the UK. The development of the FACE Risk Profile was aimed at improving on the disadvantages of existing instruments; for example, high administration costs (Iterative Classification Tree),²⁹ a forensic approach (Hare's

Psychopathy Checklist)³⁰ or not including the evaluation of risk factors in relation to damage to oneself and with very broad categories (Historical Clinical Risk-20).31 The FACE Risk Profile offers the possibility of exploring current and past risk factors in a systematic and comprehensive way. It has good psychometric properties in people with SMI and common mental disorders. 15 Its Cronbach's Alpha values for reliability are satisfactory (> 0.70), as are the Kappa index values obtained in two studies carried out to establish inter-observer agreement (Kappa = 0.90). Construct validity was examined by comparing groups of people for diagnostic criteria and use of services, with good index values obtained (p \leq 0.01). Those admitted to hospital scored higher than people treated in an outpatient setting; while people with a schizophrenia diagnosis scored higher on items related to psychotic symptoms. There were statistically significant correlations (between 0.20 and 0.70, p \leq 0.01) with most of the scores of the FACE Health and Social Assessment.¹⁵ These values indicate adequate concurrent validity, so the FACE Risk Profile was considered to be a suitable instrument for risk assessment in people with SMI.

OBJECTIVES

The overall objective of this work was to validate the version of the FACE Risk Profile risk assessment scale translated into Spanish in people with SMI. The specific objectives were to determine: (a) its reliability, including internal consistency, stability over time, test-retest reliability and inter-rater agreement; and (b) its validity, including convergent and discriminant validity.

METHODOLOGY

Design

This study used an observational, cross-sectional, descriptive and correlational design in a group of people with SMI.

Participants

The sample comprised 69 people with SMI undergoing follow-up in centres which are part of *BCN Salut Mental* and *Consorci Sanitari Integral* in Barcelona. The inclusion criteria were: (1) age range between 18 and 55 years old; (2) diagnosis of schizophrenia; recurrent major depression; manic, depressive or mixed bipolar disorder; paranoia; agoraphobia with panic attacks; obsessive compulsive disorder; borderline personality disorder or schizotypal personality; according to the International Classification of Mental and Behavioural Disorders, 10th version (ICD-10);³² (3) illness duration greater than 2 years; or (4) Global Assessment of Functioning (GAF) score³³ ≤ 50. People with dementia, organic brain damage or intellectual disability were excluded from the study.

Study variables

The main variable of the study was the risk of relapse. Secondary variables included clinical functioning, psychosocial functioning, psychiatric symptoms, suicidal risk and overt aggression.

Instruments

- FACE Risk Profile.28

The FACE Risk Profile is a semi-structured interview to assess the risk of relapse, consisting of 47 items evaluating the presence or absence of risk factors and warning signs. The interview is carried out on the evaluated person and can be supported by clinical reports about the person and other information; with the sources of information used having to be recorded in the interview protocol. The FACE Risk Profile covers the following four areas:

- 1. Administrative data and medical history.
- 2. Assessment of risk factors and warning signs, consisting of 5 subscales: Clinical symptoms indicative of risk (8 items); Behaviour indicative of risk (16 items); Indicators related to treatment (5 items); Criminal record (8 items); and Personal circumstances indicative of risk (10 items). A final item is included on other risk factors identified. Each item in this section was assessed on two different occasions: over the last year and during the last month. It consists of a description of the different risk factors identified; a summary of the measures taken in the past in relation to the risk; the opinion of the person evaluated and caregivers; and the protective factors identified.
- 3. Seven Risk indicators (violence/harm to others; suicide; intentional self-harm; serious personal neglect; accidental self-harm, abuse/exploitation by others and physical condition) are measured using a Likert-type scale from 0 (no apparent risk) to 4 (serious and imminent risk), as well as the total risk of relapse (yes/no).
- 4. Risk management plan: This describes the steps to take to minimise the risk if a relapse or risk is found.

The scores for the 7 risk indicators were used as variables in the analysis.

 Sociodemographic questionnaire and clinical history of the person. It includes sociodemographic information, use of mental health services, suicide attempts, associated medical illnesses, main diagnosis, psychiatric comorbidities, history of drug use, current medication with a psychoactive active ingredient and family history.

- Global Assessment of Functioning (GAF).³³ This scale is included in the fourth edition of the Diagnostic and Statistical Manual of Mental Disorders. It measures the clinical, social and global functioning of the person, with a score ranging from 1 (malfunction) to 100 (best possible performance). The raw score was used as a variable in the analysis.
- Short Disability Assessment Schedule, DAS-s. This assesses the functioning of people with SMI using 7 items divided into 3 sections. Only areas of specific functioning were assessed: personal care, occupational functioning, family functioning and functioning in the broad social context. Each item is scored on a 5-point scale, with 0 as the absence of the disability, and 5 severe disability most of the time. The sum of the items provides a global measure of disability: the higher the score, the higher the degree of disability. The Spanish validation in people with schizophrenia shows good psychometric properties. The raw disability score in each of the areas and the total score were used as variables in the analysis.
- Clinical Global Impression (CGI). This scale is designed to assess the severity of a person's psychopathological condition. The following areas are scored on a scale of 1 (normal, not sick) to 7 (among the most seriously ill): positive symptoms, negative symptoms, depressive symptoms, cognitive symptoms and total score. The higher the score, the more serious the psychopathological condition. The raw score for each of the areas and the total score were used as variables. The Spanish version in people with schizophrenia shows good psychometric properties.³⁶
- Plutchik Suicide Risk Scale. This records a self-assessment of suicide risk and contains 15 dichotomous items. The person can answer only 'yes' (1 point) or 'no' (0 points) in relation to questions about the previous month. The higher the score, the greater the risk of suicide. The raw scoring of the scale was used. The validation of this scale in a Spanish sample also shows good psychometric properties.²⁰
- Overt Aggression Scale. This measures different types of aggression of a person: verbal, physical against oneself, physical against objects and physical against others. Each of these types of aggression is measured from 5 items, taking into account the severity and frequency of the aggressive behaviour. Severity is assessed using a Likert-type scale that ranges between 1 (absence of aggression) and 5 (extreme severity). The frequency is scored taking into account the number of times the behaviour has occurred in a specific time, as determined by the evaluator. The total raw score of the scale was used.

The Spanish version of this scale shows good psychometric properties.^{24, 25}

Procedure

The FACE Risk Profile²⁸ was translated into Spanish as follows: (1) Initial translation: 2 translations of the FACE Risk Profile into Spanish were performed simultaneously: one by a bilingual translator, and the other by two of the project researchers. The mother tongue of the latter was Spanish, and they had a good command of English and extensive knowledge of psychopathology and psychological assessment. They were aware of the study objectives and tried to find possible ambiguities in the original items. The project coordinating group then met to create the first Spanish version of the FACE Risk Profile. (2) Comparison of the translations to compare the differences and prepare a joint version. (3) Translation of this joint version into English by a bilingual translator who had not participated in the previous process. (4) Comparison of the direct translation (to Spanish) and the reverse translation (into English) to evaluate the semantic and conceptual equivalence of the sentences. (5) Preparation of the final version, which was sent to the FACE Risk Profile authors to verify its semantic, idiomatic, cultural and conceptual equivalence. This procedure took into account cultural and linguistic differences and ensured the quality of the translation.37

Before starting the evaluation, the participants, or their guardian, were provided with information about the study, its objectives and the protocol orally and in writing, and their informed consent was requested. The evaluators received 5 hours of training on the instruments to standardise evaluation procedures and update their knowledge. The diagnosis of each participant was established by their referral psychiatrist following ICD-10 criteria.³² The FACE Risk Profile AMH v.6 validation project was approved by the Clinical Research Ethics Committee of the Catalan Hospital Union.

In the first evaluation, the participants were administered the questionnaires referred to in the instruments section. For test-retest reliability, an assessment was carried out 2 weeks later, with only the FACE Risk Profile. To evaluate the degree of inter-rater agreement, 2 raters conducted a joint evaluation of 25% of the people participating in the first evaluation.

Data analysis

Cronbach's alpha coefficient was used to assess internal consistency according to the following values: 0.60 - 0.80, adequate; 0.80-0.85, good, and > 0.85, excellent.³⁸

The Kappa coefficient was used to assess the degree of inter-rater agreement according to the following values: 0 – 0.20, very low; 0.21 – 0.40, low; 0.41 – 0.60, moderate; 0.61 – 0.80, high and 0.81 – 1.00 very high.³⁹

The stability of the scores (test-retest reliability) was calculated using the Spearman correlation coefficient for the FACE Risk Profile scores at baseline and at follow-up.

Evidence of concurrent validity focused on the relationships of the FACE Risk Profile with other variables, based on the Spearman correlation coefficient between the FACE Risk Profile scores and the scores from other instruments applied at baseline. The values of the Spearman correlation coefficient were considered as follows: r < 0.4, low; 0.4 - 0.6 medium; 0.61 - 0.80, high; and > 0.8 very high.⁴⁰

Discriminant validity was studied by establishing groups of people according to different variables: having a family psychiatric history (Yes or No), disability (DAS-s³⁴ mean total score \geq 4), severity of the disorder (CGI³⁶ mean total score \geq 4), suicide risk (Plutchick Suicide Risk Scale²⁰ mean total score \geq 6) and risk of violence (Overt Aggression Scale⁴¹ mean total score \geq 7). To evaluate the differences in the FACE Risk Profile²⁶ indices according to groups of participants, the Student's t test with the Bonferroni correction for multiple comparisons was used. The level of significance was established at $\alpha \leq$ 0.001.

RESULTS

Sample Sociodemographic and Clinical Data

The sample consisted of 69 participants, 32 women and 37 men, with a mean age of 47.62 years (standard deviation = 8.19). Most were single (68.2%) with a secondary school education level (53.6%); 37.7% of the participants lived in an institution; 85.5% were pensioners with their main source of income being contributory (39%) or non-contributory pensions (40.6%) or other (5.9%); see Table 1.

Regarding the diagnosis, 29 participants were diagnosed with schizophrenia; 1 with schizotypal disorder; 12 with recurrent depressive disorder; 6 with bipolar disorder; 10 with schizoaffective disorder, 5 with obsessive compulsive disorder; 2 with agoraphobia; and 4 with borderline personality disorder. Of the participants, 46.4% had made suicide attempts on at least one occasion and 71% of the sample had a family psychiatric history. Statistically significant differences were observed in the proportion of participants with and without a partner (χ^2 (1) = 40.710; p < 0.0001).

Table 1	· .	Sociodemographic characteristics of the participants (n = 69)				
Variable		Frequency (%)				
Sex						
Woman		32 (46.4)				
Man		37 (53.6)				
Age*		47.62 (7.22)*				
No relationship		61 (88.4)				
Single		47 (68.1)				
Separated		5 (7.2)				
Divorced		9 (13.1)				
With relationsh	ip	8 (11.6)				
Married		8 (11.6)				
Level of comple	eted studies					
Primary		23 (33.3)				
Secondary (secondary train	ondary, high school and ing)	37 (53.6)				
Superiors (higher postgraduate)	er degree, university and	9 (13.1)				
Nucleus of curi	rent coexistence					
Only		8 (11.6%)				
With partner ar	nd / or children	13 (18.7%)				
With their pare	nts	17 (24.6%)				
With a family m	With a family member or other people					
In an institution	1	26 (37.7%)				
Employment situation						
Student	1 (1.4%)					
Worker	1 (1.4%)					
Pensioner		59 (85.5%)				
Temporary / low disability 3 (4.3)						
Jobless 5 (7.4)						

^{*} media (standard deviation)

Reliability estimation

Table 2 contains the Cronbach's alpha coefficient for each FACE Risk Profile subscale. Internal consistency is adequate for most, except for Behaviour indicative of current risk and Indicators related to current treatment, which had low and very low values, respectively. The internal consistency of the Criminal Records subscale was not calculated due to the null variance.

Table 3 shows the test-retest correlations between the subscale scores and the FACE Risk Profile indices. As can be seen, the correlations between the scores on the FACE Risk Profile subscales are positive, very high and significant. Correlations between risk subscales in the past are slightly higher than between risk subscales at the present time. The test-retest correlations between the different indices are positive, significant, and range from high to very high,

Table 2	Internal consistency of the subscales of the Face Risk Profile				
Subscales		Cronbach's alpha			
Clinical sympto	Clinical symptoms indicative of past risk				
Clinical sympto	Clinical symptoms indicative of current risk				
Behavior indica	0.608				
Behavior indica	0.586				
Indicators relate	0.627				
Indicators relate	0.295				
Personal circumstances indicative of past risk					
Personal circumstances indicative of current risk 0.731					

except for the High Relapse Risk index, whose correlation is low. Correlations are not shown for the Accidental Self-Injury Risk Index and the Criminal History subscale because these variables were not observed in the study sample.

Table 3 Test retest correlation between subscales and indices of the Face Risk Profile (n = 69)						
Subscales		Spearman's correla- tion coefficient				
Clinical symptor of past risk	ns indicative	0.881*				
Clinical symptor current risk	0.800*					
Behavior indicat	ive of past risk	0.890*				
Behavior indicat	0.776*					
Indicators relate	0.846*					
Indicators relate	0.796*					
Personal circums past risk	0.810*					
Personal circums current risk	0.881*					
Risk of violence	0.818**					
Suicide risk	0.809**					
Risk of intention	0.671**					
Risk of serious p	0.844**					
Risk of abuse / e	0.855**					
Risk related to p	0.741**					
High risk of relapse 0.315**						

^{*} p<0,05; ** p<0,01

Inter-rater agreement was very high (Kappa = 1) for all FACE Risk Profile subscales, except for the Personal Circumstances Indicative of Risk subscale, where a good degree of agreement was obtained (Kappa = 0.778 in the past and 0.760 in the present).

Evidence of validity

Table 4 shows the Spearman correlations between the FACE Risk Profile index scores and the scores for the other scales used in the study.

The correlations between the FACE Risk Profile scores and the GAF indices are negative, very low or low, and not significant, except for the correlations between the Risk of abuse/exploitation by others index and the total and clinical GAF which are negative, low and significant, and the correlations between the physical state index and the clinical GAF, which are negative, low and significant.

Only 3 FACE Risk Profile indices show positive and statistically significant correlations with the DAS-s: the serious personal risk/neglect index has a low correlation with the

DAS-s personal care; the abuse/exploitation by others index has a low correlations with DAS-s personal care, DAS-s functioning in a broader social context and total DAS-s, and is moderate with DAS-s family functioning; the physical condition index shows low correlations with all areas of the DAS-s, except with DAS-s personal care, which is very low and not significant.

The FACE Risk Profile indices show moderate to low, positive and significant correlations with the total CGI score, except for the Risk indices for serious personal neglect, accidental self-harm and abuse/exploitation by others which have positive, low and non-significant correlations.

The Suicide risk index shows positive, low and significant correlations with CGI negative symptoms, and positive, moderate and significant correlations with CGI depressive symptoms; the risk index for intentional self-harm shows positive, moderate and significant correlations with CGI depressive symptoms; the exploitation by others risk index shows positive, low and significant correlations with CGI depression and positive cognitive symptoms, moderate and significant with CGI positive symptoms; finally, the physical

Table 4 Correlations between indices of the Face Risk Profile and the rest of psychosocial measures (n = 69)							
	Risk of vio- lence / harm to others	Suicide risk	Risk of in- tentional self-harm	Risk of serious per- sonal aban- donment	Risk of acci- dental self- harm	Risk of abuse / exploitation by others	Risk related to physical condition
Social GAF	114	008	183	143	206	189	080
Clinical GAF	219	127	221	138	062	388**	286*
Total GAF	132	097	162	106	116	280*	187
DAS-s personal care	084	036	021	.353**	.120	.398**	.048
DAS-s occupational functioning	.067	016	.160	115	014	.000	.287*
DAS-s familiar functioning	.159	.005	.081	.193	.004	.536**	.276*
DAS-s functioning in a broader social context	.136	019	.169	.002	.034	.252*	.241*
DAS-s total	.084	052	.101	.132	.042	.399**	.259*
CGI positive symptoms	.061	.169	.213	.086	.153	.426**	.246*
CGI negative symptoms CGI síntomas negativos	059	.246*	.216	.223	.230	.128	.257*
CGI depressive symptoms	.172	.411**	.438**	.151	.217	.250*	.475**
CGI cognitive symptoms	.074	.046	.186	.055	.091	.304*	.199
CGI total score	GI total score .250* .304		.423**	.139	.190	.222	.393**
Plutchick Suicide Risk Scale	.307*	.576**	.483**	.376**	.306*	.293*	.495**
Overt Agression Scale	.513**	.293*	.562**	.324**	.340**	.156	.125

^{*}p<0.05; **p<0.01GAF: Global Assessment of Functioning; DAS-s: Disability Assessment Schedule Short Form; CGI: Clinical Global Impression

state risk index has positive, low and significant correlations with CGI positive symptoms and negative symptoms, and positive, moderate and significant with CGI depressive symptoms.

All FACE Risk Profile indices show positive, low or moderate, and significant correlations with the Plutchik Suicidal Risk and Overt Aggression scale scores, except for the abuse/exploitation by others risk index and the physical state risk index which have very low and non-significant correlations with the Overt Aggression scale.

Table 5 shows the differences between the FACE Risk Profile index scores according to groups of participants. No statistically significant differences were observed according to the presence or absence of a family psychiatric history. Statistically significant differences were observed between the groups of participants established according to clinical and psychosocial variables. Specifically, the participants with disabilities had significantly higher violence towards others risk index scores. The group of participants with a high risk of suicide had higher scores in the risk indices for Suicide, self-harm and physical condition. Finally, the group of participants with a high risk of violence had higher risk index scores for violence/harm to others.

DISCUSSION

The aim of this study was to present the validation in Spanish of the FACE Risk Profile²⁸ for people with SMI. In general, the FACE Risk Profile showed good psychometric properties in this population.

The internal consistency values were adequate for Behaviour indicative of current risk and Indicators related to current treatment, which were low and very low, respectively. Our results are similar to those of the original FACE Risk Profile validation for internal consistency. In this study, all Cronbach's Alpha values were satisfactory (> 0.70). In our study, all values were close to 0.70 except for the two aforementioned subscales, which showed little variability in their scores. One possible explanation is that the sample consisted of people with SMI treated in the community setting and with clinical stability, which probably homogenised the scores on these subscales.

Inter-rater agreement was very high or high for the FACE Risk Profile subscales, and were similar to those obtained in the original FACE Risk Profile¹⁵ validation study, where the Kappa index values for inter-observer agreement were 0.90. To date, no further studies have been conducted on the reliability of the FACE Risk Profile.

Table 5	Differences between the scores of the face indices Risk profile, according to groups of participants Student's t							
		Risk of violence / harm to others	Suicide risk	Risk of intentional self-harm	Risk of serious per- sonal aban- donment	Risk of acci- dental self- harm	Risk of abu- se / exploi- tation by others	Risk related to physical condition
. ,	hiatric family history amily psychiatric ante-	1.22	2.16	0.65	0.75	0.30	-0.44	0.55
Disabled vs. with DAS-s \geq 4 vs. to	out disability (total tal DAS-s < 4)	3.76**	0.447	0.19	0.65	0.21	1.02	1.33
	erity vs. low clinical an total score ≥ 4 vs. score < 4)	2.00	1.95	3.17	1.65	1.08	1.57	2.25
(Suicide Risk Sca	c vs. without suicide risk le mean total score ≥ 6 scale mean total score	1.910	5.17**	3.97**	3.08	2.13	1.95	5.07**
(Manifest Aggres	te vs. No risk of violence ssion Scale total mean nifest Aggression Scale • < 7)	3.53*	1.82	3.35	1.96	1.76	0.58	0.66

^{*} p<0.001; ** p<0.0001

DAS-s: Disability Assessment Schedule Short Form; CGI: Clinical Global Impression

The concurrent validity of the FACE Risk Profile indices range from low to moderate. Negative and low or very low correlations were obtained between the FACE Risk Profile index scores and GAF scores. Participants with greater clinical difficulties do not have a greater risk. These results are consistent with those of the original validation study²⁸ in which a relatively low correlation was observed between the degree of severity of the disorder and the presence of risk, and it was concluded that global scores derived from scales such as GAF cannot be considered measures of risk.

People with greater disabilities in family functioning also showed a greater risk of abuse/exploitation by others. The scientific literature highlights that people with SMI are more vulnerable to victimisation by others and indicates the use of substances, greater clinical symptoms or being homeless, among others, as associated factors. ^{42,43} Disability in family functioning in our study was measured through the DAS-s, which allowed an evaluation of this functioning in the broadest sense, and could be related to prominent factors such as being homeless. It is recommended that future research goes farther in the study of the relationship between these variables.

Participants who were at higher risk of self-harm showed a greater number of depressive symptoms and greater severity of the disorder. Our results are consistent with those of other studies in which it has been found that suicide attempts are significantly associated with greater severity of the disorder.^{44,45,46}

Participants with a higher risk of abuse/exploitation by others had more positive symptoms, which is consistent with the scientific literature analysed previously.^{42,43} People with a high risk in relation to their physical condition have more depressive symptoms and greater severity of the disorder. Our results were similar to those of other recent studies that show a direct relationship between physical health and severity of the disorder.^{47,48,49,50}

People with a higher risk of suicide on the Plutchik Suicide Risk Scale also had a higher risk of suicide, self-harm, serious personal neglect and physical condition risk.²⁰ People with a higher risk of violence on the Overt Aggression Scale²⁴ had a higher risk of violence or harm to others, self-harm, serious personal neglect and accidental injury. This observed association is congruent with the results of a systematic observational study review and meta-analysis in which overt aggression, evaluated with the same instrument used in this study, showed a direct relationship with levels of aggression towards oneself or others.⁵¹ These results support the concurrent validity of the FACE Risk Profile.

Also, some Risk indices such as violence, suicide, selfharm and that related to physical condition were able to discriminate between groups of participating people according to the level of disability, the severity of the disorder and the risk of suicide or violence.

To our knowledge, this is the first work on the Spanish validation of the FACE Risk Profile. Concurrent validity of the FACE Risk Profile had been established, up to now, only with the FACE Health and Social Assessment, ¹⁵ which is not a specific scale for risk assessment. Future research should include other scales that take into account other risk areas considered in the FACE Risk Profile.

Among the limitations of the work are the small sample size, which may have had an influence on the lack of statistically significant differences being detected between the groups of participants in the FACE Risk Profile indices. Also, as our sample had relative clinical stability while being attended to in the community setting, showed little variability in some of the FACE Risk Profile subscale and index scores, which could have repercussions on the temporal stability of the scores and the internal consistency of the subscales. New studies with larger samples, evaluating groups of patients with SMI, both in the community and institutional setting are needed. Longitudinal studies are also necessary to associate the presence of risk with remission or exacerbation of psychopathological symptoms, both in people with SMI and with other types of psychopathological disorders.

CONCLUSIONS

The FACE Risk Profile has good reliability and validity, which supports its use in the population with SMI. The FACE Risk Profile could be considered for use in the risk assessment of people with SMI for both research and routine clinical practice purposes. To the best of our knowledge, the FACE Risk Profile is the first psychometric instrument validated in Spanish for the comprehensive and systematic assessment of risk factors in a particularly vulnerable population group. It can be considered a useful tool for relapse prevention and risk management. Future research on the FACE Risk Profile could include studying its psychometric properties in other populations.

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Conflicts of interest. The authors declare they have no conflict of interest related to this work.

References

- Morgan S. Introduction. En: Morgan S. ed. Clinical risk management. A clinical tool and practitioner manual. London: The Sainsbury Centre for Mental Health; 2000. p. 1-2.
- 2. Melle I, Barrett EA. Insight and suicidal behaviour in first-episode schizophrenia. Expert Rev Neurother. 2012;12(3):353-9.
- 3. Saha S, Chant D, McGrath J. A systematic review of mortality in schizophrenia: is the Is the Differential Mortality Gap Worsening Over Time? Arch Gen Psychiatry. 2007; 64(10):1123-1131.
- Caldwell CB, Gottesman II. Schizophrenics kill themselves too: a review of risk factors for suicide. Schizophr Bull. 1990;16(4):571-89.
- 5. Palmer BA, Pankratz VS, Bostwick JM. The lifetime risk of suicide in schizophrenia: a re-examination. Arch Gen Psychiatry. 2005;62(3):247-53.
- Haw C, Hawton K, Sutton L, Sinclair J, Deeks J. Schizophrenia and deliberate self-harm: a systematic review of risk factors. Suicide Life Threat Behav. 2005;35(1):50-62.
- Wiersma D, Wanderling J, Dragomirecka E, Ganev K, Harrison G, An Der Heiden W, et al. Social disability in schizophrenia: its development and prediction over 15 years in incidence cohorts in six European centres. Psychol Med. 2000;30(5):1155-67.
- 8. Hawton K, Sutton L, Haw C, Sinclair J, Deeks JJ. Schizophrenia and suicide: systematic review of risk factors. Br J Psychiatry; 2005;187: 9–20.
- 9. Fazel S, Gulati G, Linsell L, Geddes JR, Grann M. Schizophrenia and violence: systematic review and meta-analysis. PLoS Med. 2009;6(8):e1000120.
- Fazel S, Langstrom N, Hjern A, Grann M, Lichtenstein P. Schizophrenia, substance abuse, and violent crime. JAMA. 2009;301(19):2016-23

- 11. Soyka M, Graz C, Bottlender R, Dirschedl P, Schoech H. Clinical correlates of later violence and criminal offences in schizophrenia. Schizophr Res. 2007; 94(1-3):89-98.
- 12. Large MM, Ryan CJ, Singh SP, Paton MB, Nielssen OB. The predictive value of risk categorization in schizophrenia. Harv Rev Psychiatry. 2011;19(1):25–33.
- 13. Murrie DC, Cornell D, McCoy WK. Psychopathy, conduct disorder, and stigma: Does diagnostic labelling influence juvenile probation officer recommendations? Law Hum Behav. 2005;29(3):323-42.
- 14. Buchanan A, Sint K, Swanson J, Rosenheck R. Correlates of Future Violence in People Being Treated for Schizophrenia. Am J Psychiatry. 2019;176(9):694-701
- 15. Clifford P. The National Outcome Audit of Severe Mental Illness. Report to the Department of Health. London: CORE, University College of London; 2001. Available at: https://imosphere.com/care-and-support-tools/
- Sarró S, Dueñas RM, Ramírez N, Arranz B, Martínez R, Sánchez JM, et al. Cross-cultural adaptation and validation of the Spanish version of the Calgary Depression Scale for Schizophrenia. Schizophr Res. 2004;68(2-3):349-56.
- 17. Touriño R, Acosta FJ, Giráldez A, Álvarez J, González JM, Abelleira C, et al. Suicidal risk, hopelessness and depression in patients with schizophrenia and internalized stigma. Actas Esp Psiquiatr. 2018;46(2):33-41.
- Peralta V, Cuesta MJ. Validation of the positive and negative syndromes scale (PANSS) in a sample of Spanish schizophrenics. Actas Luso Esp Neurol Psiquiatr 1994;22(4):171-7.
- 19. Plutchik R, van Praag HM. The measurement of suicidality, agressivity and impulsivity. Prog Neuropsychopharmacol Biol Psychiatr. 1989; 13 (Suppl): 23-4.
- 20. Rubio G, Montero I, Jáuregui J, Salvador M, Marín JJ, Santo-Domingo J. Validation of the Plutchick suicide risk scale in the Spanish population. Arch Neurobiol (Madr). 1998; 61(2):143-52.
- 21. Rubio G, Montero I, Jáuregui J,Martínez ML, Álvarez S,Marín JJ y cols. Validation of the Plutchik impulsivity scale in the Spanish population. Arch Neurobiol (Madr). 1998; 61: 223–232.
- 22. Plutchik R, van Praag HM. A self-report measure of violence risk, II. Compr Psychiatry. 1990; 31(5): 450-6.

- Rubio G, Montero I, Jáuregui J, Salvador M, Marín JJ, Santo-Domingo J. Validation of the Plutchik violence risk scale in the Spanish population. Arch Neurobiol (Madr). 1998; 61: 307- 16.
- 24. Arango C, Calcedo Barba A, González-Salvador, Calcedo Ordóñez A. Violence in inpatients with schizophrenia: a prospective study. Schizophr Bull. 1999;25(3):493-503.
- 25. Rivera Bedoya, Navia Bueno. Validation of the "manifest aggressiveness scale" in psychotic patients treated in the emergency service of the university clinic hospital. Magazine "Cuadernos". 2017; 58(2): 28-34.
- 26. Vargas M, Quintanilla P, Vega B, Lozano A. FEAFES Castile and Leon Psychosocial Risk Scale (ERP): construction procedure using qualitative methodology and presentation of the scale. Northern Mental health. 2010;8(38):26–35.
- 27. Vargas M, Quintanilla P, Lozano A, Sendra-Gutiérrez JM and "FEAFES-CyL Investigation Group. Psychosocial risk associated with ageing in severe mental disorder: validation and assessment of the FEAFES Castile and León Psychosocial Risk Scale (ERP). Psychosocial Rehabilitation. 2013; 10(1): 3-10.
- 28. Clifford P. FACE profile. London: Research Unit, Royal College of Psychiatrists; 1993.
- Monahan J, Steadman H. Towards a Rejuvenation of Risk Assessment Research. En: Violence and Mental Disorder, Monahan J and Steadman H, ed. Chicago: University of Chicago Press; 1996. p. 1–17.
- 30. Hare RD. A Research Scale for the assessment of psychopathy in criminal populations. Pers Individ Dif. 1980; 1(2),111-9.
- 31. Douglas KS, Ogloff JR, Nicholls TL. Assessing risk for violence among psychiatric service users: the HCR-20 violence risk assessment scheme and the Psychopathy Checklist: Screening Version. J Consult Clin Psychol. 1999;67(6):917-30.
- 32. World Health Organisation. International Statistical Classification of Diseases and Related Health Problems, version 10. Geneva: World Health Organisation; 1992.
- 33. American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 4th ed. Washington DC: American Psychiatric Association; 1994.
- 34. Janca A, Kastrup M, Katschnig H, López-Ibor JJ, Mezzich

- JE, Sartorius N. The World Health Organisation short disability assessment schedule (WHO DAS-S): a tool for the assessment of difficulties in selected areas of functioning of patients with mental disorders. Soc Psychiatry Psychiatr Epidemiol. 1996;31(6):349-54.
- 35. Mas-Expósito L, Amador-Campos JA, Gómez-Benito J, Lalucat-Jo L. The World Health Organisation short disability assessment schedule: a validation study in patients with schizophrenia. Compr Psychiatry. 2012;53(2):208-16.
- 36. Haro JM, Kamath SA, Ochoa S, Novick D, Rele K, Fargas A, et al. The Clinical Global Impression–Schizophrenia scale: a simple instrument to measure the diversity of symptoms present in schizophrenia. Acta Psychiatr Scand Suppl. 2003;(416):16–23.
- 37. Guillemin F, Bombardier C, Beaton D. Cross Cultural Adaptation of Life Measures: Literature Review and Proposed Guidelines. J Clin Epidemiol. 1993;46:1417-32.
- 38. Haertel EH. Reliability. En: Brennan RL, ed. Educational measurement. Wesport, CT: American Council on Education and Praeger Publishers; 2006. p. 65–110.
- 39. Altman DG. Practical statistics for medical research. New York, NY: Chapman and Hall; 1991.
- 40. Cohen J. Statistical power analysis for the behavioural sciences. 2nd ed. New Jersey: Lawrence Erlbaum; 1988.
- 41. Fresán A, Apiquian R, De la Fuente-Sandoval C, García-Anaya M, Nicolini H. Sensitivity and specificity of the Explicit Aggression Scale in patients with schizophrenia. Actas Esp Psiquiatr 2004;32(2):71–5.
- 42. Maniglio R. Severe mental illness and criminal victimisation: a systematic review. Acta Psychiatr Scand. 2009;119(3):180-91.
- 43. Tsigebrhan R, Shibre T, Medhin G, Fekadu A, Hanlon C. Violence and violent victimisation in people with severe mental illness in a rural low-income country setting: a comparative cross-sectional community study. Schizophr Res. 2014;152(1):275-82.
- 44. Jakhar, Beniwal, Bhatia, Deshpande. Self-harm and suicide attempts in Schizophrenia. Asian J Psychiatr. 2017;30:102-106.
- 45. Aydın M, Ilhan BC, Tekdemir R, Çokünlü Y, Erbasan V, Altınbaş K. Suicide attempts and related factors in schizophrenia patients. Saudi Med J. 2019;40(5):475-482.

- 46. Hor K, Taylor M. Suicide and schizophrenia: a systematic review of rates and risk factors. J Psychopharmacol. 2010;24(4 Suppl):81-90.
- 47. Abdul Rashid NA, Nurjono M, Lee J. Clinical determinants of physical activity and sedentary behaviour in individuals with schizophrenia. Asian J Psychiatr. 2019; 4(46):62-7.
- 48. Ang MS, Nurjono M, Lee J. The effects of clinical illness severity and physical activity on health-related quality of life in schizophrenia. Qual Life Res. 2019; 28(6):1509-20.
- 49. Stubbs B, Vancampfort D, Hallgren M, Firth J, Veronese N, Solmi M, et al. EPA guidance on physical activity as a treatment for severe mental illness: a meta-review of the evidence and Position Statement from the European Psychiatric Association (EPA), supported by the International Organization of Physical Therapists in Mental Health (IOPTMH). Eur Psychiatry. 2018;54:124–144.
- Dauwan M, Begemann MJ, Heringa SM, Sommer IE. Exercise Improves Clinical Symptoms, Quality of Life, Global Functioning, and Depression in Schizophrenia: A Systematic Review and Meta-analysis. Schizophr Bull. 2016;42(3):588-99.
- 51. Li W, Yang Y, Hong L, An FR, Ungvari GS, Ng CH, Xiang YT. Prevalence of aggression in patients with schizophrenia: A systematic review and meta-analysis of observational studies. Asian J Psychiatr. 2020;47:101846.