#### **ORIGINAL PAPER**



# Assessment of Basic Family Relationships: Portuguese Validation of the "Cuestionario de Evaluación de las Relaciones Familiares Básicas" (CERFB)

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#### **Abstract**

Clinical intervention with families benefits from the accurate evaluation of family dynamics, requiring the development of assessment instruments that allow for a systematic data collection and comprehension of family relations. The present study aimed to examine psychometric properties – factor structure, reliability and convergent and divergent validity – of the Portuguese Version of the "Cuestionario de Evaluación de las Relaciones Familiares Básicas" (CERFB – Basic Family Relations Questionnaire), using two non-clinical convenience samples with adult couples, having at least one biological child in common (older than 11 years old) living with them. Sample 1 included 150 participants (75 couples, analysed independently), aged between 31 and 61 years-old; sample 2 comprised 228 participants (114 couples, analysed independently), aged between 30 and 73 years-old. An Exploratory Factor Analysis was conducted with sample 1, replicating the factor structure of the original version of the CERFB (two factors – marital and parental). A Confirmatory Factor Analysis was conducted with sample 2, confirming the hypothesized model supported by good fit indexes. Results regarding reliability (assessed through Cronbach's Alpha) and convergent and divergent validity (using the Portuguese versions of the Dyadic Adjustment Scale and the Parental Stress Scale) indicate the appropriateness of CERFB in Portuguese context as a useful measure to simultaneously assess marital and parental dimensions of family functioning.

Keywords Family relations · Psychometric properties · Assessment · Parental relationship · Marital relationship

### **Highlights**

- Clinical intervention with families benefits from the accurate evaluation of family dynamics.
- Portuguese Version of the "Cuestionario de Evaluación de las Relaciones Familiares Básicas" replicated the factor structure of the original version of the questionnaire, assessed by EFA and CFA.
- Reliability and convergent and divergent validity indicate the appropriateness of CERFB in Portuguese context.

#### Introduction

Families and family functioning are increasingly common research topics, considering their importance, their impact

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on members' lives and the role they play in individual development and (non) adaptation throughout the life-cycle. Family as a developmental context allows its members to fulfill their needs to explore personal attributes and identities (Alarcão, 2006). In this field, researchers have identified the need for the development of assessment instruments that allow for a systematic data collection and comprehension of family's processes and dynamics, also giving light to family clinical therapists' interventions.

Adopting a family systemic perspective, continuous and interdependent interactions are assumed to occur and define family (Granic & Hollenstein, 2003) as a whole, also taking into account the parental and marital subsystems' relational specificities (Holmes, Sasaki, & Hazen, 2013). It is assumed

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that these subsystems are mutually interdependent throughout the family's life cycle, with changes in one of them (e.g. parental stress) having an impact in other (e.g. marital conflict), underlying the dynamic functioning of family relations (Goldenberg et al., 2017). Several life events can influence family dynamics (namely in the Marital and Parental subsystems), which, in turn, might influence the development and adaptation of the different family members (Harland et al., 2002).

Within this framework, and considering the relevance of simultaneously assessing both marital and parental functioning, Ibáñez, Linares, Vilaregut, Virgili and Campreciós (2012) developed the Cuestionario de Evaluación de las Relaciones Familiares Básicas (CERFB - Basic Family Relations Questionnaire). The CERFB is based upon Linares' Basic Family Relations Theory (1996, 2001, 2006, 2008, 2012), which emphasizes the conjoint marital and parental functions to the family's relational atmosphere. These two dimensions are then assumed to coexist in two independent and bipolar vectors, with marital functions ranging from Harmony to Disharmony and parental functions from Preservation to Deterioration. Linares suggests (2006) that these vectors allow the assessment of a family's ability of Relational Nurturing (according to its member's perception of experiencing love, both at emotional, cognitive and pragmatic levels within the family), as seen in Fig. 1.

In Fig. 1 four basic relational groups can be distinguished: (i) the upper right quadrant is the only one comprised of the ideal conditions with regard to relational nurturing, where marital and parental functions are both preserved and couples are able to successfully solve

conflicts and adequately attain parental functions. These families are therefore considered good contexts for optimal development; (ii) the lower right quadrant represents the families with disharmonious marital functions, couples lacking the ability to solve conflicts, where, regarding parenthood, adults might engage one of their children in alliances or coalitions, resulting various forms of triangulation; (iii) the upper left quadrant represent the families where adults are able to function as a couple but unable to accomplish parental functions, emotionally depriving their children; (iv) the lower left quadrant represents families with both deteriorated marital and parental functions, favouring a chaotic relational atmosphere.

Ibáñez et al. (2012) administered CERFB to a nonclinical convenience sample of 221 Spanish couples (442 participants), aged between 27 and 71 years-old (M = 52.4; SD = 6.7) with children aged between 11 and 36 years-old (M = 20.6; SD = 5.7). This study concluded that the instrument has appropriate psychometric properties (Cronbach's alphas of 0.91 and 0.92 for parental and marital scales, respectively). As theorized, CERFB simultaneously evaluated marital and parental functions, allowing for the distinction between functional and dysfunctional couples as well as competent and inadequate parental functions. The psychometric properties of the CERFB were also examined with samples of families of patients with psychosis (Roca et al., 2020) and eating disorders (Campreciós et al., 2020). In these studies, psychometric properties of the CERFB were, again, adequate.

Considering these results and the proven usefulness of CERFB on assessing simultaneously the parental and

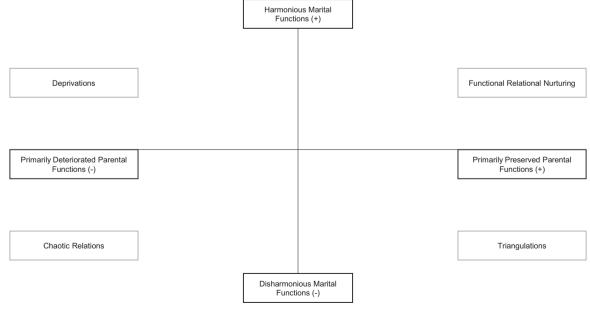


Fig. 1 Basic family relations theory (adapted from Linares, 2008, 2012).



marital families' functioning and, in this sense, its relational nurturing both with non-clinical and clinical families, supporting Linares' model, the interest to adapt it to other cultures grew. This was the case in Italy (Vilaregut, Callea, Campreciós, Coletti, Mercadal, & Mateu, 2019), with CERFB being administered to a non-clinical convenience sample of 228 participants (114 heterosexual couples) aged between 34 and 69 years (M = 51.70, SD = 6.04). Psychometric data from this study replicated CERFB's original structure, consistent with the conceptual framework from which it was developed, supporting its validity, as also seen when considering the correlations established with other instruments for convergent and divergent validity analyses. Furthermore, Cronbach's alpha of the Marital factor was 0.92 and Parental factor was 0.80, results that demonstrate Italian version of CERFB as a reliable one.

In the Portuguese context, no measures directed to simultaneously assess parenting and couple's functioning are available, although the topics addressed are assumed to be highly relevant to family evaluation and therapy, as can be noticed in the proliferation of instruments focused in the marital axis (e.g. Escala de Avaliação da Satisfação em Áreas da Vida Conjugal – Marital Life Satisfaction Scale, Narciso & Costa, 1996; Medida Global de Satisfação no Relacionamento - Global Measure of Relationship Satisfaction - GMREL - Pascoal, Oliveira & Raposo, 2015) and the parental axis (e.g. Escala de Autoeficácia Parental -Parental Self-efficacy Scale, Brites & Nunes, 2010; Escala de Sentimento de Competência Parental - Parenting Sense of Competence, Ferreira et al., 2011; Escala de Preocupações Parentais - Parenting Worries Scale, Algarvio & Leal, 2004).

Considering this gap, this study aims to examine CERFB's dimensional structure and reliability in a Portuguese sample, and to assess its convergent and divergent validity with established measures of the family constructs addressed (parental and marital functions), using the Portuguese versions of the Dyadic Adjustment Scale (DAS; Gomez & Leal, 2008) and the Parental Stress Scale (PSS; Leal & Maroco, 2010).

The first aim of this study was to examine psychometric properties of the items and to explore and confirm the structure of CERFB and its reliability. The second aim was to verify the instrument's convergent and divergent validity with established measures of other family constructs, by studying the association between the Marital and Parental scales of the CERFB, the four scales of the DAS, and the PSS. Marital Functioning, assessed by CERFB, is expected to be positively correlated to Dyadic Adjustment, assessed by the DAS, and Parental Functioning, assessed by CERFB, is expected to be negatively correlated to Parental Stress, assessed by PSS.



# **Translation and Adaptation of CERFB**

The Portuguese adaptation of CERFB included: (1) the items were translated from Spanish to Portuguese by a family psychotherapist, native speaker of Portuguese; (2) this pilot questionnaire was presented to five native Portuguese professionals within the psychological and psychiatric sector for an inter-rater evaluation through a semistructured questionnaire; this expertise group was asked whether they had doubts or suggestions to make which would improve the clarity of items; (3) on the basis of this information, the final version of the Portuguese CERFB was established and sent to a Portuguese professional interpreter for its backward translation to Spanish; (4) the Portuguese pilot version of the instrument was administered to a small convenience sample of Portuguese adults, in order to assess item comprehension; (5) both Spanish versions (the original version and the one that resulted from the backward translation) were compared to verify that the meaning of the items in both of them was the same to avoid significant modifications in the instrument.

# **Participants**

#### Sample 1

Sample 1 consisted of 150 participants equally divided by gender (75 couples) aged between 31 and 61 years (M = 49.79, SD = 6.04). Regarding children, 32% had one child, 54.7% had two children, 11.3% had three children and 2.0% had four children. The age the first (or only) child ranged from 11 to 37 years-old (M = 20.85, SD = 5.61). On average, the couples were living together for 24.09 years (SD = 5.99). In relation to the marital status, 91.3% of the couples were married for the first time, 2.0% for the second time and 6.7% were cohabitant partners. Regarding education, 33.20% of the partners held a university degree, 47.10% a high school degree and the remaining 19.70% have completed basic school (first through ninth grades).

# Sample 2

Sample 2 included 228 participants equally divided by gender (114 couples), aged between 30 and 73 years (M = 48.23, SD = 7.02). Regarding children, 37.8% had one child, 53.8% had two children, 7.6% had three children and 0.9% had four children. The age the first (or only) child ranged from 11 to 38 years-old (M = 20.16, SD = 5.81).On average, the couples were living together for 23.11 years (SD = 6.20). In relation to the marital status, 92.9% of the



couples were married for the first time, 1.3% for the second time and 5.8% were cohabitant partners. Regarding education, 23.70% of the partners held a university degree, 32.10% a high school degree and the remaining 44.20% have completed basic school.

#### Measures

The Cuestionario de Evaluación de las Relaciones Familiares Básicas (CERFB; Ibáñez et al., 2012) is a 25 item self-reported pencil and paper measure of family relations that is based on Linares's theory. Items are rated on a five-point rating scale that increases in frequency and that ranges from 1 (never) to 5 (always). The second order factor analysis of the original version showed a bi-dimensional structure: the Marital scale (14 items; e.g. "My partner and I make a good team"; "I think my partner and I disagree about most things") and the Parental factor (11 items; e.g. "I like to spend my free time with my children"; "my children often get on my nerves"). The reliability of the Spanish validation was very high for both the Marital scale (Cronbach's alpha = 0.92) and the Parental factor (Cronbach's alpha = 0.91).

The Portuguese version of *Dyadic Adjustment Scale* (Gomez & Leal, 2008) is a 32 item self-reported pencil and paper measure that evaluates marital adjustment. Thirty of its items are rated on a five to seven-point rating scale ranging from *never* to *always*, and two items have dichotomous *yes* or *no* answers, with higher global scores reflecting higher marital adjustment. In the Portuguese validation study of the DAS, validity was examined using confirmatory factor analyses, and reliability was assessed using Cronbach's *alpha*. Alphas ranged from 0.66 (Affectional Expression Scale) to 0.90 (Total Scale) (Gomez & Leal, 2008).

The Portuguese version of *Parental Stress Scale* (Leal & Maroco, 2010) is an 18-item self-report measure with a 5-point rating scale, assessing experienced parental stress. The Portuguese validation study supported the four-factor structure of the PSS and showed good reliability scores, with Cronbach's *alpha* ranging from 0.57 and 0.78; total scale's *alpha* = 0.76 (Leal & Maroco, 2010).

# **Data Collection Procedures**

The questionnaires were administered between January and February 2016 (sample 1), and between March and May 2016 (sample 2) in northern Portugal. Access to participants was obtained through personal contacts from the research team, as well as through a snowball procedure. The participation was voluntary and anonymity of all participants was guaranteed. The questionnaires were self-rated by participants, who were instructed to consider the current moment when responding the items, and sent to the research team by pre-paid mail. The study protocol included a written explanation of the study and

its goals, and written informed consent was obtained from all individual participants. Inclusion criteria entails being Portuguese, part of a heterosexual couple of adults (aged between 18 to 75 years-old), and having at least one biological child in common (older than 11 years old) living with them. The study protocol was approved by the Ethics Committee of Ramon Llull University in Barcelona, as part of a larger project conducted by the research team.

# **Data Analysis Procedures**

Using sample 1, in order to test whether each item had a normal distribution, descriptive statistics, skewness and kurtosis were performed. An exploratory factor analysis (EFA) of the CERFB through the principal component analysis method using the IBM SPSS Statistics 21 software was then performed. To test sampling adequacy, we measured Kaiser–Meyer–Olkin (KMO) and Bartlett's test of sphericity. The number of components extracted was based on the percentage of variance accounted for the Kaiser-Guttman method and, overall, the scree plot (Mazza et al., 2012).

In order to test the factor structure that emerged from the exploratory model, we performed a confirmatory factor analysis (CFA), through structural equation modelling by the use of LISREL 8.54 (Jöreskog & Sörbom, 2001), considering sample 2. To test the goodness of fit, we considered absolute fit indices as standardised root mean square residual (SRMR) and root mean square error adjustment (RMSEA) and incremental fit indices as comparative fit index (CFI), incremental fit index (IFI) and non-normed fit index (NNFI). Furthermore, we considered chi-square divided by degrees of freedom ( $\chi^2/df$ ). As suggested by Byrne (1998), a model can be considered reasonably standard if SRMR and RMSEA are lower than 0.08, if CFI, IFI and NNFI are higher than 0.90 and if  $\chi^2/df$  is <3.

Reliability was tested through Cronbach's *alpha* in order to measure internal consistency. Furthermore, in order to test discriminating power of polytomous items, the corrected point-biserial correlation ( $cr_{pb}$ ) was calculated.

Pearson's correlation coefficients between CERFB scales, DAS scales and PSS total scale score were calculated to assess the convergent and divergent validity.

Although both samples were composed by couples and some measures assume the dyadic structure of the data, all analyses were conducted independently for all the participants.

## **Results**

### **Preliminary Analyses**

Mean, standard deviation, skewness and kurtosis for each item were calculated, in order to test whether the



Table 1 Mean, Standard Deviation, Skewness and Kurtosis for each item of the CERFB

	Mean	Standard deviation	Skewness	Kurtosis	
Item 1	2.63	0.95 0.51		0.43	
Item 2	2.20	0.83 0.63		0.79	
Item 3	3.95	1.11 -0.78		-0.41	
Item 4	2.25	1.14 0.67		-0.32	
Item 5	4.25	0.91 $-1.31$		1.61	
Item 6	2.34	1.02	1.02 0.78		
Item 7	1.90	0.91	0.80	-0.15	
Item 8	4.11	0.87	-1.02	1.22	
Item 9	2.01	0.96	0.95		
Item 10	1.87	1.05	1.27	1.12	
Item 11	4.17	0.92	-1.04	0.81	
Item 12	4.11	0.95	-0.91	0.16	
Item 13	4.37	0.82	-1.38	1.85	
Item 14	2.27	1.04	0.69	0.00	
Item 15	2.18	0.98	0.86	0.52	
Item 16	3.85	1.04	-0.71	-0.18	
Item 17	3.76	1.04	-0.66	-0.03	
Item 18	2.04	1.04	0.85	0.05	
Item 19	3.95	1.07	-0.87	-0.08	
Item 20	4.30	0.88	-1.25	1.18	
Item 21	2.26	0.83	0.99	1.51	
Item 22	2.00	0.84	0.75	0.22	
Item 23	1.66	0.75	0.94	0.40	
Item 24	2.17	0.94	0.75	0.24	
Item 25	3.79	1.04	-0.56	-0.53	

distribution was approximately normal (see Table 1). Results showed that no item had extreme means or standard deviation close to zero; furthermore, skewness and kurtosis were between -1 and +1, except for five items for which they were slightly lower or higher. In sum, the results suggested that the item distribution can be considered approximately normal.

# **Exploring the Structure of the CERFB**

On sample 1, we explored the dimensional structure of the CERFB through principal component analysis. In the preliminary analysis, the sample results are adequate as seen by KMO = 0.89 and Bartlett's ( $\chi^2$  (300) = 1788.88; p < 0.001). The scree plot suggests that two factors, with eigenvalues > 1, should be extracted, explaining 49.06% of the total variance. Communalities ranged between 0.25 and 0.75, suggesting that each item is well represented by the factorial model. Table 2 shows the component loading matrix, eigenvalues and the percentages of variance accounted for each factor.



**Table 2** Exploratory Factor Analysis - Component loading matrix, eigenvalues and the percentages of variance accounted for each dimension

	Marital scale	Parental scale	cr <sub>pb</sub>
ITEM19_ Marital	0.86		0.83
ITEM12_ Marital	0.83		0.81
ITEM25_ Marital	0.83		0.83
ITEM11_ Marital	0.82		0.77
ITEM16_ Marital	0.81	-0.25	0.81
ITEM17_ Marital	0.79		0.77
ITEM7_ Marital	-0.78		0.76
ITEM24_ Marital	-0.78		0.74
ITEM3_ Marital	0.75	-0.26	0.73
ITEM9_ Marital	-0.73		0.71
ITEM22_ Marital	-0.72		0.66
ITEM6_ Marital	-0.71	0.21	0.66
ITEM10_ Marital	-0.68		0.64
ITEM14_ Marital	-0.66	0.27	0.66
ITEM15_ Parental		-0.75	0.48
ITEM21_ Parental		-0.66	0.43
ITEM23_ Parental		-0.59	0.40
ITEM4_ Parental		-0.58	0.43
ITEM8_ Parental	0.22	0.55	0.47
ITEM2_ Parental		-0.55	0.40
ITEM1_ Parental		-0.50	0.36
ITEM20_ Parental	0.25	0.50	0.43
ITEM18_ Parental	-0.33	-0.42	0.40
ITEM5_ Parental	0.28	0.41	0.40
ITEM13_ Parental		0.27	0.26
Eigenvalues	9.52	2.75	
Explained variance	38.08%	10.98%	

Results show that all the items of each dimension load only in one factor, presenting a correlation of at least 0.30, except for item 13 (-0.27). The first factor includes items related to the Marital dimension. The second factor includes items directed to assess the Parental dimension. This item distribution replicates the factor structure of the Spanish version.

Table 2 also reports the corrected point-biserial correlation coefficients ( $cr_{pb}$ ) between each item and total score of the scale without the analyzed item; the results showed that the discriminating power of items was adequate. In particular, the corrected point-biserial correlation coefficients varied from 0.66 to 0.86 for marital factor and from 0.26 to 0.48 for parental factor.

### **Confirmatory Factorial Analysis (CFA)**

Based on the results of the principal component analysis, a confirmatory factor analyses was conducted on sample 2

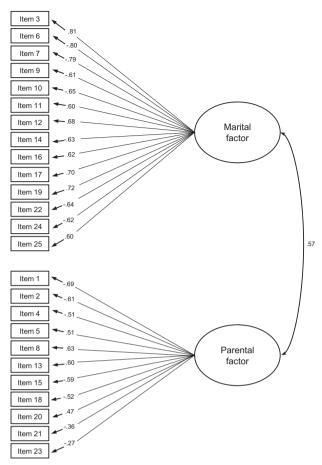


Fig. 2 Confirmatory factor analysis (Standardized solution): Structural equation modelling.

(Fig. 2), with 2 latent variables (the Marital factor and the Parental factor, represented in the ellipses) and 25 observed variables (the items, represented in a box).

The hypothesized model appears to be a reasonably good fit to the data: the SRMR was 0.07, the RMSEA was 0.08, the CFI was 0.92, and the NNFI was 0.90; the  $\chi^2/df$  was 2.62 (716.46/274).

# Reliability, Convergent and Divergent Validity

Table 3 reports the Cronbach's alpha for each dimension of the CERFB and the Pearson correlations between the CERFB's factors and DAS dimensions and PSS total score.

The Marital and Parental factors presented good internal consistency coefficients suggested by Cronbach's alpha scores of 0.92 and 0.81, respectively. CERFB's Marital factor was positively correlated to the four DAS scales and negatively correlated to the PSS total score. CERFB's Parental factor presented a strong negative correlation with the PSS total score and a positive correlation with three DAS scales. These results suggest good convergent and

divergent validity of the CERFB with other measures of dyadic adjustment and parental stress.

Gender differences were examined in CERFB's dimensions. The results of the independent samples t test show no significant differences between male and female participants in both Marital [t(206,809) = -0.74, p = 0.46] and Parental [t(209) = 0.65, p = 0.51] factors. The correlation between participants' age and CERFB's dimensions scores showed only a negative correlation between age and the Marital factor (r = -0.14, p < 0.05). Furthermore, considering the participants' children's age range and its potential impact on the quality of the parental dimension, a correlation analysis was conducted between children's age and CERFB's Parental factor. Results show no significant correlations between these two variables (r = -0.09, p = 0.18).

### **Discussion**

This study aimed to examine the psychometric properties of CERFB in Portugal. The EFA in this study replicated the factor structure of the CERFB's Spanish and Italian versions (Ibáñez et al., 2012; Vilaregut et al., 2019): a Marital factor with 14 items and a Parental factor with 11 items. This structure reflects the two functions described in the basic family relations theory Linares (1996, 2001, 2006, 2012). The use of CFA in the Portuguese study allowed confirming the validity of the factor model based on both the EFA results and the theoretical background of the CERFB, assuring its usefulness for the assessment of marital and parental functions in Portuguese families.

Concerning CERFB's internal consistency, Cronbach's alpha coefficient for the Marital and Parental factor were high and in line with Spanish and Italian data (Ibáñez et al., 2012; Vilaregut et al., 2019).

The Marital factor of CERFB was positively and significantly correlated with the DAS sub-scales, with participants who reported higher levels of marital functioning presenting higher dyadic adjustment. Regarding Parental dimension, it was significantly negatively correlated to the PSS, suggesting that participants reporting higher levels of parental functioning experience lower parental stress. These associations support the convergent and divergent validity of the Portuguese version of CERFB. Linares (2012) considers that parental system's functioning might undermine marital functioning in case parenting is compromised or, on the opposite perspective, enhance parents' functioning as a couple. Moreover, Linares (2012), emphasizing the mutual influences that encompass marital and parental functioning, also suggests that marital relations may threaten parental quality or strengthen it. This perspective is in line with



**Table 3** Cronbach's alpha and correlations

	1	2.	3	4	5	6	7
	1		3	+	3	0	
CERFB - Marital	0.92						
CERFB - Parental	0.53**	0.81					
DAS - Dyadic Consensus	0.56**	0.25**	0.90				
DAS - Dyadic cohesion	0.64**	0.33**	0.81**	0.72			
DAS - Dyadic satisfaction	0.56**	0.27**	0.59**	0.63**	0.77		
DAS - Affectional expression	0.26**	0.01	0.43**	0.32**	0.27**	0.74	
PSS – Total score	-0.41**	-0.66**	-0.16*	-0.26**	-0.25**	0.12	0.85

<sup>\*</sup>p<0.05; \*\*p<0.01 values along main diagonal are alpha coefficients for scaled variables

Robbins et al. (2003), who highlight the complexity of family functioning, stressing that the family subsystems (in this case, marital and parental ones) mutually influence each other.

Overall, the good psychometric properties of the Portuguese version of CERFB demonstrate its usefulness for assessing the basic family relations through marital and parental functions as described by Linares (1996, 2012), overcoming the lack of instruments available to Portuguese researchers and clinicians interested in simultaneously evaluating these two dimensions of family functioning. This is the third country – following Spain and Italy – where CERFB's psychometric properties were evaluated and results show similar dimensional structure, reliability scores, and discriminant and convergent validity. These results support the usefulness of this measure in these southern European countries, which can also be related to the fact that they share common values concerning family.

Future research should examine CERFB's temporal stability, sensitivity - through age and gender differences in participants and their children, considering developmental specificities throughout individual's and families' life cycle, which might be relevant to the families' functioning in both Parental and Marital dimensions. Furthermore, expanding data collection with clinical groups, as is the case in Spain (Campreciós et al., 2014, 2020; Roca et al., 2020), will allow to: (1) confirm the psychometric appropriateness of the measure in clinical settings; (2) examine if CERFB accurately discriminates between general population samples and different clinical groups of families. A comparative study of a sample of parents of patients with psychosis and a non-clinical group showed the accuracy of CERFB distinguishing the two groups of families (Campreciós et al., 2020). Replication of these results with other clinical groups, will contribute to the design of adequate intervention and prevention programs, and monitoring of their outcomes, through identifying cut-off scores, considering the axes of harmonious/disharmonious marital function, and primarily preserved/deteriorated parental function. In community intervention settings (e.g., NGOs working with families facing psychosocial risk), CERFB may be used as a screening measure for the identification of priorities in psychosocial intervention, as well as a follow-up tool for evaluating the effectiveness of standardised interventions.

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# **Compliance with Ethical Standards**

Conflict of Interest The authors declare no competing interests.

**Ethical Approval** All procedures performed in the included studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed Consent** Informed consent was obtained from all individual participants included in the study.

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