



Fear of cancer recurrence inventory (FCRI) in Spanish: validation in Mexican women with breast cancer

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Título: Inventario de Miedo a la Recurrencia del Cáncer (FCRI) en español: validación en mujeres mexicanas con cáncer de mama.

Resumen: *Antecedentes/Objetivo.* El Inventario de miedo a la recurrencia del cáncer (FCRI, por sus siglas en inglés) evalúa el miedo a la recurrencia de forma multidimensional y propone un punto de corte clínico. Sin embargo, hasta la fecha aún no existe una versión traducida al español del FCRI. Este estudio tiene como objetivo evaluar las propiedades psicométricas de la versión española del FCRI en mujeres que completaron el tratamiento primario para cáncer de mama. *Material y Métodos.* Se siguieron las recomendaciones de la Comisión Internacional de Pruebas para la adaptación cultural. 267 que completaron el tratamiento primario para el cáncer de mama participaron y respondieron a la versión en español del FCRI y a la Escala de Necesidades de Apoyo. *Resultados.* Se exploraron dos modelos usando AFC, el modelo de segundo orden $\chi^2(807, n = 265) = 1500.3, p < .001, \chi^2/gf = 1.85, CFI = .89, TLI = .89, RMSEA = .057$ (90% intervalo de confianza = 0.052–0.061), y el modelo de siete factores relacionados $\chi^2(791, n = 265) = 1391.7, p < .001, \chi^2/gf = 1.75, CFI = .91, TLI = .90, RMSEA = .053$ (intervalo de confianza del 90% = .049–.058) obtuvo un ajuste adecuado. Los valores de alfa de Cronbach obtenidos fueron de adecuados a buenos y el índice de correlación interclase fueron aceptables para cinco de las siete dimensiones (.68 a .83). *Conclusión.* La versión en español del FCRI tiene propiedades psicométricas adecuadas para uso clínico y de investigación en poblaciones mexicanas.

Palabras clave: Inventario de miedo a la recurrencia del cáncer. Mujeres con cáncer de mama. Versión en español. Sobreviviente de cáncer. México. Fiabilidad.

Abstract: *Background/Objective.* The Fear Cancer Recurrence Inventory (FCRI) evaluates fear cancer recurrence multidimensionally and proposes a clinical cutoff point. However, there has yet to be a translated Spanish version of the FCRI to date. This study aims to evaluate the psychometric properties of the Spanish version of the FCRI in women who completed primary treatment for breast cancer. *Material and Methods.* Recommendations of the International Test Commission were followed for cultural adaptation. Two hundred sixty-seven women who completed primary treatment for breast cancer participated in and responded to the Spanish version of the FCRI and the Supportive Care Needs Survey. *Results.* Two models are explored using AFC, the second order model $\chi^2(807, n = 265) = 1500.3, p < .001, \chi^2/gf = 1.85, CFI = .89, TLI = .89, RMSEA = .057$ (90% confidence interval = .052–.061), and the seven related factors model $\chi^2(791, n = 265) = 1391.7, p < .001, \chi^2/gf = 1.75, CFI = .91, TLI = .90, RMSEA = .053$ (90% confidence interval = .049–.058) obtained an optimal fit. Adequate-to-good Cronbach's alpha values and the interclass correlation index were acceptable for five of the seven dimensions (.68 to .83). *Conclusion.* The Spanish version of the FCRI has psychometric properties suitable for clinical and research use in Mexican populations.

Keywords: Fear of cancer recurrence inventory. Breast cancer women. Spanish version. Cancer survivor. Mexico. Reliability.

Introduction

Breast cancer (BC) survivors face physical and emotional challenges following active treatment. Fear of cancer recurrence (FCR) is one of the most common emotional problems affecting breast cancer women (Cessna et al., 2020; Hall et al., 2019).

As a commonly reported unmet need among cancer survivors, FCR is defined as "fear, worry or concern relating to the possibility that cancer will come back or progress" (Lebel, Simard, Harris, Feldstain & Devins, 2016, pp. 3267). It is estimated that 73% of patients experience FRC, 49% experience moderate-to-high intensity, and 7% experience high intensity. In Mexico, studies of unmet needs reported that between 37% and 60% of women with BC experienced FCR as a critical psychological unmet need (Gálvez-

Hernández et al., 2021; Suchil-Bernal, Rodríguez- Velázquez, Galindo & Meneses, 2016).

FCR has been unconsciously related to sociodemographic variables such as age, sex, education, marital status, and having children and to clinical aspects such as type of cancer, stage of cancer, and type of treatment (Smith et al., 2020). However, some studies show that female patients, young, with a partner and with children present more significant FCR, together with the type of treatment such as chemotherapy and time of diagnosis of less than five years (Simard et al., 2013; Fang, Fetzer, Lee & Kuo, 2018; Koch-Gallenkamp et al., 2016; Krok-Schoen, Naughton, Bernardo, Young & Paskett, 2018).

The evaluation of the FCR is relevant because, although it can be considered part of the adaptation to the survival stage at low levels, its clinical severity affects the survivor's quality of life (Ozga et al., 2015; Peng et al., 2019). It has been observed that five years after diagnosis and after completing their treatments, survivors continue to have FCR. This problem is related to increased visits to health services, anxiety, depression, and the use of anxiolytics and antidepressants, which negatively affect the quality of life of BC

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(Article received: 27-10-2023; revised: 22-05-2024; accepted: 03-06-2024)

survivors (Koch-Gallenkamp et al., 2016; Champagne, Ivers & Savard, 2018; Tran et al., 2022; Yang et al., 2023).

More than 20 instruments were used to evaluate FCR. The FCR inventory (FCRI) measures the construct multidimensionally and is recommended when FCR is the goal to be evaluated. This instrument has also shown adequate and consistent psychometric properties in a heterogeneous sample of the population with cancer (Smith et al., 2020). Likewise, the FCRI proposes a clinically significant cutoff point, which can be used as the gold standard for making clinical decisions (Thewes et al., 2012). A recent meta-analysis has confirmed its properties and established it as the most widely used clinical instrument for evaluating FCR. It is also reported that this measure has been translated and validated from French to English, Chinese, Danish, Mandarin, Persian, Turkish, Korean, Dutch and several others (Smith et al., 2020; Shin et al., 2017; van Helmond, van der Lee & de Vries, 2017); however, the FCRI is not currently available in Spanish. Notably, despite this language being the third most spoken in the world, no FCR assessment instrument accurately detects the levels and intensity of FCR in Spanish-speaking survivors, limiting any clinical activity designed to assess and treat this problem.

Therefore, this study aimed to evaluate the psychometric properties of the Spanish version of the FCRI in women who underwent primary BC treatment in Mexico.

Method

Patients with breast cancer have a greater chance of survival than other types of cancer, depending on the location and stage at which the cancer is detected. For example, the 5-year survival of breast cancer patients is between 99-86% if it is localized (American Cancer Society, 2024) compared to colorectal cancer, whose survival can be between 90-65% (Asociación Española Contra el Cáncer; 2021). Breast cancer in Mexico tends to occur in younger women, that is, compared to women in the United States and Europe, where it occurs at 63 years of age, in Mexican women it occurs in the age range of 41 and 50 years, almost 10 years earlier, and another characteristic compared to other countries is that breast cancer is detected in advanced stages in Mexico (Maffuz-Aziz, Labastida-Almendaro, Espejo-Fonseca, & Rodríguez-Cuevas, 2017). In this study the participants were women diagnosed with BC who attended different health institutions and met the following inclusion criteria: patients who completed their primary treatment for BC, were older than 18 years, and agreed to participate voluntarily. Patients with recurrent BC or a history of other types of cancer were excluded. This study was approved by the Ethics and Research Committee of the National Cancer Institute (021/015/IBI) (CEI/1562/21). Data were collected from October 2019 to December 2022. The rule of Anastasi and Urbina (1998) was followed to define the sample size with a minimum sampling of five participants for each item. The instrument had 42 items multiplied by five, giving a sample of 210 participants.

Therefore, we decided to apply 250, considering possible missing data.

Instruments

The FCRI evaluates the FCR in a multidimensional manner. It consists of 42 items that measure seven dimensions: 1) triggers (8 items) evaluate specific situations that suggest the possibility of cancer recurrence, and one item evaluates the extent to which these situations are generally avoided; 2) severity (9 items) assesses the presence, frequency, intensity, and duration of thoughts associated with FCR. This subscale is referred to as the FCRI-short version, and the recommended cut-off point for clinical FCRI screening is obtained ≤ 13 . Also, it is defined as the perceived risk of recurrence, legitimacy of worrying about cancer recurrence, and the presence of other unpleasant thoughts or images that come to mind in association with a reverse item that assesses one's belief that one is cured; 3) psychological distress (4 items) includes four types of emotions often triggered by thoughts about cancer recurrence; 4) coping strategies (9 items) include strategies that can be used to cope with FCR; 5) functional alterations (6 items) include domains of functioning that can be disturbed by FCR; 6) insight (3 items) assesses the degree to which patients perceive their fear as excessive or unreasonable; and 7) reassurance seeking behaviors (3 items). The items are rated on a Likert scale of 0 to 4 points; the higher the score, the higher the FCR level. It has a Cronbach's alpha of .95, temporal stability ($r = .89$), and construct validity with other self-report scales assessing FCR ($r = .68$ to $.70$) or related constructs such as psychological distress ($r = .43$ to $.77$) and quality of life ($r = -.20$ to $-.36$) (Simard & Savard 2009).

The Supportive Care Needs Survey, Spanish version, consists of 34 items divided into five dimensions: 1) psychological needs (10 items), 2) health systems and information needs (11 items), 3) physical activity and daily living needs (5 items), 4) care needs (5 items), and 5) needs related to sexuality (3 items). A five-point Likert scale (0 to 4) measures whether a patient needs support and the extent of such a need; a high score indicates a high need. The validation in Spanish has Cronbach's alpha values ranging from .78 to .90 (Dobova, Aguirre-Hernandez, Gutiérrez-de la Barrera, Infante-Castañeda & Pérez-Cuevas, 2015).

Procedure

Translation

The guidelines of the International Test Commission on the use of tests in research, quality control, and safety were followed for cultural adaptation (Muñiz, Elosua & Hambleton, 2013). The relevance of assessing the construct when identifying the needs of medical staff in a clinic was identified. Previously described literature and indicators in our country were also reviewed, although the FCR has not been

directly evaluated in Mexico. Subsequently, permission to adapt and the necessary documents were requested from the instrument's author, Dr Simard. After that, we proceeded to cultural translation. A native professional performed the process of translating the text from English to Spanish, and a specialist in English and terminology in the health area (Translation 1). Subsequently, another independent translator native to the original language of the instrument and a specialist in the Spanish language and terminology in the areas of health performed the back-translation of the instrument (Translation 2). The research team (two experts in scale development and validation and two experts in clinical and health psychology) and the original author of the scale reviewed the equivalence of both versions in English: the original and the back translation. When the equivalence was accepted, pilot testing was implemented using the revised translation in the format of an individual interview with ten BC women survivors. The patients commented that the instructions, items, and answer options were clear; therefore, no modifications were made to the questionnaire, and the final application was carried out.

Administration

With the final version, the instrument was administered in person; however, due to the COVID-19 contingency, adjustments were made to administer the questionnaire through Google Forms and by telephone. To complete Fear Cancer Recurrence Inventory in all modalities, the participants received aid from a trained research psychologist, they received training in the management of the instrument, the instructions, the response options, and the importance of following the implementation procedures (Barahona, García, Sánchez-García, Barba & Galindo-Villardón, 2018). For those who provided their data to participate in a second application of the FCRI, a telephone call was made 4 to 6 weeks after the first application to obtain test-retest reliability.

Data analysis

Data were analyzed using SPSS-AMOS 23. As a first objective on the factorial structure, we contrasted the model of Simard and Savard (2009), confirmatory factor analysis (CFA) was performed, in which a second-order model with three levels, items (42), main factors (seven subscales), and the second factor (FRC) was tested. The CFA was also explored with the seven related factors. For the chi-square likelihood ratio statistic, comparative fit index (CFI) and root-mean-square error of approximation (RMSEA) were used as indicators of the good fit of the model. The goodness-of-fit criteria for each index were CFI, TLI > .90, and RMSEA < .06. To assess convergent validity, Spearman's correlation coefficient was obtained between the FCRI subscales and

the dimensions of the support needs questionnaire. Because the criteria of the parametric tests are not met, discriminant validity was assessed using the Mann-Whitney U test to compare sociodemographic and medical characteristic between FCRI scored dimensions. Variables such as age, number of children, type of treatment and time of diagnosis have been related to greater fear of recurrence (Simard et al., 2013; Fang, Fetzter, Lee & Kuo, 2018; Koch-Gallenkamp et al., 2016; Krok-Schoen et al., 2018). As reliability indicators, Cronbach's alpha and the intraclass correlation coefficient (ICC) were obtained to assess the test-retest reliability, performed by telephone between 4 and 6 weeks after the first administration.

Results

Description of the sample

It involved 267 women who had completed their primary treatment for BC in the age range of 28 to 86 years; most were married, with children, did not work outside the home, and practiced some religion. Regarding the clinical data, 39% had another chronic disease and a family member with cancer; most had stage II ductal BC and had received surgery, chemotherapy, and radiotherapy (Table 1).

Construct validity

In the CFA, a second-order model with seven factors was initially proposed according to the reported FRCI model. The parameters obtained with adjustment covariance items were significant, and the goodness of fit statistics are good values χ^2 (807, $n = 265$) = 1500.3, $p < .001$, $\chi^2/df = 1.85$, CFI = .89, TLI = .89, RMSEA = .057 (90% confidence interval = .052–.061). The explained variance of each factor was in a range of .73 to .94. The CFA with the seven related factors and adjustments in the covariance of the items obtained acceptable model fit indicators χ^2 (791, $n = 265$) = 1391.7, $p < .001$, $\chi^2/df = 1.75$, CFI = .91, TLI = .90, RMSEA = .053 (90% confidence interval = .049–.058). The correlations between the factors are strong (.543 to .727) and significant, except for the coping strategies and reassurance dimension, which has weak correlations with all other dimensions (Figure 1).

Reliability

Cronbach's alpha with adequate to good values (.71 to .92) was obtained for all dimensions of the FCRI. Acceptable ICC values for test-retest reliability were obtained for functional alterations, psychological distress, insight, and severity (Table 2).

Table 1
Description of the sample ($n = 267$)

	Mean (Standard Deviation)
Age	53 (10)
Monthly income USD	381.29 (1736.3)
Level of education (years)	7.9 (5)
	Frequency (%)
Marital status	
Single	59 (22.1)
Married/with partner	167 (62.5)
Separated/divorced	25 (9.4)
Widower	16 (10.0)
Children	
Yes	225 (84.3)
No	42 (15.7)
Employed	
Yes	100 (37.5)
No	167 (62.5)
Religion practice	
Yes	257 (98)
No	10 (2)
Other Disease	
Yes	105 (39.3)
No	162 (60.3)
History of cancer Family	
Yes	105 (39.3)
No	162 (60.7)
Type of cancer	
Ductal	112 (41.9)
Lobular	17 (6.4)
Triple negative	6 (2.2)
Hormonal	10 (3.7)
Undefined	122 (45.7)
Cancer stage	
0	6 (2.2)
I	57 (21.3)
II	93 (34.8)
III	59 (22.1)
IV	26 (9.7)
Undefined	26 (9.7)
Cancer treatments received	
Surgery (SG)	32 (12)
Chemotherapy (QH)	9 (3.4)
Radiotherapy (RT)	4 (1.5)
SG+RT	24 (9.0)
SG+QH	47 (17.6)
SG+RT+QH	149 (55.8)
Not defined	2 (.7)
Time of diagnosis	
≤ 5 years	207 (78.4)
> 5 years	57 (21.3)
Current treatment	
Yes	95 (35.7)
No	171 (64.3)

Figure 1
Path diagram of the Spanish version of FCRI

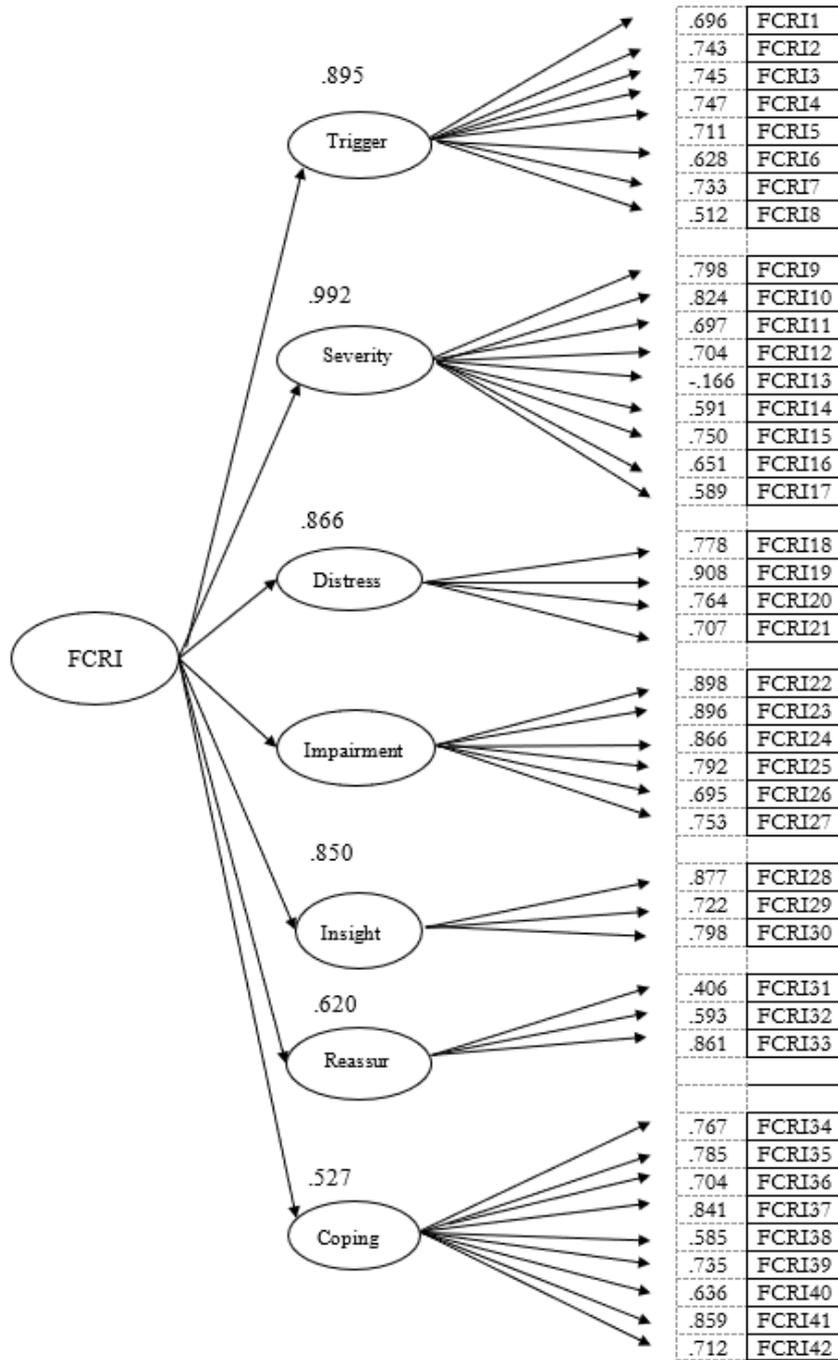


Table 2
Item correlations, reliability and test-retest of FCRI

FCRI	Number of items	Mean (SD) <i>n</i> = 267	Alpha	Items correlation	Alpha Retest <i>n</i> = 52	ICC [95%CI] <i>n</i> = 52
Triggers	8	10.3 (6.5)	.86	.42-.72	.91	.69 [.47, .82]
Psychological Distress	4	4.9 (4.1)	.89	.55-.69	.83	.83 [.70, .90]
Functioning Impairments	6	4.2 (5.5)	.92	.56-.74	.90	.74 [.56, .85]
Insight	3	2.6 (3.0)	.86	.72-.75	.74	.81 [.67, .89]
Severity	9	11.8 (6.4)	.84	.03-.75	.79	.86 [.76, .92]
Coping strategies	9	21.6 (3.0)	.87	.54-.72	.89	.68 [.44, .81]
Reassurance	3	2.7 (2.5)	.71	.25-.39	.73	.68 [.44, .81]
FCRI Total Score	42	63.6 (27.3)	.94	.13-.74	.94	.87 [.44, .81]

Note. *SD* = Standard Deviation. FCRI = Fear of Cancer Recurrence Inventory. ICC = Interclass Correlation Coefficient. *CI* = Confidence Interval

Convergent validity

Table 3 shows the positive and significant relationships between the dimensions of the FCRI and those of the Supportive Care Needs Survey, except for coping strategies where no significant relationships were found. Notably, the highest test correlations were between psychological needs and FCRI dimensions such as: psychological distress ($r = .542, p < .01$), functioning impairments ($r = .584, p < .01$), insight ($r = .576, p < .01$) and severity ($r = .555, p < .01$).

Table 3
Correlation analysis between FCRI subscales and Supportive Care Needs dimensions

Care Needs/FCRI	Triggers	Distress	Functioning Impairments	Severity	Reassurance	Coping strategies	Insight	FCRI Total
Psychological	.46**	.54**	.58**	.55**	.34**	.02	.57**	.50**
Health system and information	.33**	.34**	.37**	.33**	.34**	-.00	.37**	.35**
Physical & daily living	.33**	.33**	.41**	.30**	.30**	.11	.34**	.37**
Patient care & support	.27**	.29**	.36**	.30**	.28**	-.01	.30**	.30**
Sexuality	.22**	.21**	.22**	.24**	.21**	-.01	.21**	.24**

Note. FCRI = Fear of Cancer Recurrence Inventory. ** $p \leq .01$

Discriminant validity

Significant differences were obtained in psychological distress between women under 40 and over 41 years old ($\chi^2 = -2.50, p = .01$). Significant differences were found between women who have and do not have a partner in the dimensions of psychological distress ($\chi^2 = -2.36, p = .01$), functioning alteration ($\chi^2 = -2.13, p = .03$), severity ($\chi^2 = -2.42, p = .01$) and FCRI total ($\chi^2 = -2.08, p = .02$). The coping strategies dimension was significantly different between women with and without children. ($\chi^2 = -2.27, p = .01$). Concerning clinical variables, only significant differences were found between no current treatment vs surveillance treatment on the reassurance dimension ($\chi^2 = -2.08, p = .03$). No significant differences were found when comparing other variables such as employment, religious practice, history of cancer family, clinical stage, time of diagnosis (less than five years vs five years).

Discussion

This study assessed the psychometric characteristics of the Spanish version of the FRCI in women undergoing primary treatment for breast cancer. The back-translation process was completed, the equivalence of the two versions was evaluated, and the final application was performed once ap-

proved. Regarding the factorial structure obtained in this Spanish version, the original structure was maintained with 42 items divided into seven factors. The two models evaluated obtained optimal indicators, similar to what was obtained in other versions (Lebel et al., 2016; Simard & Savard, 2009; Liu et al., 2017). However, other versions, such as the Turkish version, have proposed 4-factor models with appropriate model fit (Eyrenci & Sertel Berk, 2018).

In this study, some items obtained a low factorial load and correlation, but it was decided to keep them because they did not improve the fit indicators of the model; item 13 was one of those considered relevant within the severity dimension with which the clinical score for FCR was obtained, although it was the one that came out lower. It was decided to maintain them to keep equivalence with other versions (Shin et al., 2017). This finding may be due to the difficulty in understanding the item because of its inverse structure with the answer options and because it comprises two statements, one of which presents a negation. Therefore, it is suggested to improve the writing.

Regarding convergent validity, the relationship between the FRCI and Supportive Care Needs Survey dimensions was correlated, similar to that reported by Otto, Soriano, Siegel, LoSavio and Laurenceau (2018). In other words, the greater the FRC, the greater the demand for medical attention in services and information, indicating that this psychological phenomenon is related to unmet needs for services

and information. This result is consistent with studies showing that information needs are associated with mental health deterioration, elevated anxiety and stress levels, and an increased risk of depressive symptoms (Barr, Hill, Farrelly, Pitcher & White, 2020; Luutonen, Vahlberg, Eloranta, Hyväri & Salminen, 2011; Sarkar et al., 2015; Schmid-Büchi, Halfens, Müller, Dassen & van den Borne, 2013). Similarly, it was found that psychological needs were related to psychological distress, functional alterations, insight, severity and total FCRI, which coincides with another study that associated FCRI with more significant anxiety and depression and with lower quality of life (Eyrenci & Sertel, 2018). All FCRI and total FCRI dimensions were associated with more needs, indicating convergent validity.

The FRC coping strategies dimension was not significantly related to any dimension of the Supportive Care Needs Survey and shows different directions among them. In the original version (French), the relationships with quality of life indicators are low, positive and significant (Simard & Savard, 2009); however, in the English version this same relationship between variables is negative and significant with quality of life indicators (Lebel et al., 2016). This variability in the results exposes the need to further review this heterogeneity. The result obtained could be related to the fact that the coping strategies scale includes the exploration of two types of coping strategies, cognitive and behavioral, which could cause the women to respond to both, depending on their needs. However, these results highlight the need for further studies about the relationship between these variables.

Regarding discriminant validity, younger women presented higher levels of FCR in dimensions such as reassurance, psychological distress, and altered functioning. These results are similar to those reported in other studies, such as that being young is related to higher FCR (Krok-Schoen et al., 2018; Shay, Carpentier & Vernon, 2016). Similarly, other instrument versions have shown negative correlations between age and FCR (Simard & Savard, 2009; Hovdenak et al., 2018). This relationship is consistent with similar studies that emphasized that young women with BC are more biopsychosocially vulnerable than those over 50 (Villarreal-Garza,

Lopez-Martinez, Muñoz-Lozano & Unger-Saldaña, 2019). However, like in another study, no found relationship between medical variables such as the time of diagnosis (Custers et al., 2017). Therefore, more research is needed on young Latin American women and their FCR.

The reliability index obtained was acceptable to good in all dimensions, with the lowest being the dimension of insight and the highest being that of functioning alterations, similar to the original version (Simard & Savard, 2009), and the range obtained was similar to that obtained in the other versions (Shin et al., 2019; Liu et al., 2020). This consistency was likely because the original psychometric structure was maintained.

The results of this study describe only patients with BC and should be considered with caution, given that the instruments were administered in different modalities. Despite this, there is evidence that face-to-face interviews, telephone, and online and offline questionnaires do not differ significantly on scales of stress, depression, and anxiety; in addition, these scales maintain their psychometric properties (van Ballegooijen, Riper, Cuijpers, van Oppen & Smit, 2016; Zhang, Kuchinke, Woud, Velten & Margraf, 2017).

The Spanish-language adaptation of the FCRI, may contribute to the assessment, diagnosis, and investigation of FCR in Spanish-speaking BC survivors and, eventually, to the accurate and culturally adapted assessment and intervention of this problem for these survivors. In the natural process of this line of research, we recommend the continuation of the data collection to add validity and reliability indicators in different cancer patients who speak Spanish to generalize the results.

Complementary information

Acknowledgements.- Requests for permission to use the FCRI (any language versions) should be addressed to Sébastien Simard: Sebastien1_Simard@uqac.ca

Financial support.- No funds

Conflict of interest.- The authors declare no conflict of interest.

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