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## The Persian Version of the Fear of Cancer Recurrence Inventory (FCRI): Translation and Evaluation of Its Psychometric Properties

Fatemeh Sadat Bateni<sup>a</sup>, Maryam Rahmatian<sup>b</sup>, Ahmad Kaviani<sup>c,d,e</sup>, Sebastian Simard<sup>f</sup>, Mehdi Soleimani<sup>b</sup>, Ali-Akbar Nejatisafa<sup>\*b,g,h</sup>

<sup>a</sup> Department of Psychiatry, University of Social Welfare & Rehabilitation, Tehran, Iran

<sup>b</sup> Department of Psychiatry, Tehran University of Medical Sciences, Tehran, Iran

<sup>c</sup> Department of Surgery, Tehran University of Medical Sciences, Tehran, Iran

<sup>d</sup> Breast Cancer Research Center, Tehran University of Medical Sciences, Tehran, Iran

<sup>e</sup> Department of Surgical Oncology, University of Montreal, Montreal, Canada

<sup>f</sup> Institut Universitaire de Cardiologie et de Pneumologie de Québec, Laval University, Québec City, Canada

<sup>g</sup> Psychosomatic Research Center, Tehran University of Medical Sciences, Tehran, Iran

<sup>h</sup> Research Center for Cognitive and Behavioral Sciences, Tehran University of Medical Sciences, Tehran, Iran

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### ABSTRACT

**Background:** This study aimed to translate and validate the Fear of Cancer Recurrence Inventory (FCRI) questionnaire into Persian and to investigate its psychometric properties.

**Methods:** The FCRI was translated to Persian using a linguistic methodology according to WHO guidelines. A total of 450 breast cancer survivors who had the following inclusion criteria were included: time elapse of more than six months after the treatment prior to the study; absence of objective markers of recurrence, fluency in the Persian language, and signing the informed consent. Internal consistency was estimated with Cronbach's  $\alpha$  coefficient and test-retest reliability with Interclass correlation. Concurrent validity was estimated through Pearson's correlation between the FCRI and Hospital Anxiety and Depression Scale (HADS). Principal component analysis (PCA) and confirmatory factor analysis (CFA) were employed to evaluate dimensionality.

**Results:** The Persian version was acceptable for patients. The content validity index (CVI) was 0.80. The instrument had good test-retest reliability (ICC= 0.96) and internal consistency (Cronbach's  $\alpha$ =0.86). PCA and CFA indicated that the factor structure of the Persian version was similar to the original questionnaire and had acceptable goodness of fit. Correlations between the FCRI and HADS was remarkable ( $r= 0.252 - 0.639$ ), indicating acceptable concurrent validity.

**Conclusions:** The Persian version of FCRI could be considered a good cross-cultural equivalent for the original English version. The questionnaire was a reliable and valid instrument in terms of internal consistency, test-retest reliability, and dimensionality.

### Address for correspondence:

Ali-Akbar Nejatisafa, MD,  
 Associate Professor, Department of Psychiatry, Psychosomatic  
 Research Center, Tehran University of Medical Sciences  
 Address: Roozbeh Hospital, South Kargar Avenue, Tehran  
 13337, Iran. Tel: +98-21-55412222  
 Fax: +98-21-55419113  
 E-mail: [nejatisafa@tums.ac.ir](mailto:nejatisafa@tums.ac.ir)

### Introduction

The number of cancer survivors has increased more than threefold over the last 30 years. Among patients with recently diagnosed cancer, nearly two-thirds are expected to survive five or more years.<sup>1,2</sup> Psychosocial problems are common in cancer survivors. Fear of cancer recurrence (FCR) is one of



these problems, which is estimated to involve 50-89% of cancer survivors. Two main definitions have been used for FCR: The first is defined as the “fear that cancer could return or progress in the same place or in another part of the body”<sup>3</sup>, which adopts a patient’s perspective of FCR and is relevant across the cancer trajectory. The second is “the degree of concern about the chances of cancer returning at a future time”; this definition emphasizes recurrence more than progression.<sup>4,5</sup> These patients constantly express the need for help, which, unfortunately, is not addressed by cancer care systems, as reported by 20 to 40 percent of patients.<sup>6-11</sup>

It is essential to screen for FCR using an appropriate measure. Several screening tools have been introduced in the literature, including subscales of more comprehensive psychosocial and quality-of-life assessment tools, brief FCR questionnaires, and longer FCR instruments.<sup>10</sup> Lack of a widely-accepted definition for FCR and the use of measures with different cut-off scores may explain an alternative approach for the assessment of FCR as well as variability in its reported prevalence rate.<sup>10,11</sup>

Fear of Cancer Recurrence Inventory (FCRI) is a 42-item multidimensional questionnaire that is appropriate for all cancer patients. Items were developed based on a cognitive-behavioral formulation of FCR<sup>12</sup>, literature review, and DSM-IV diagnostic criteria. The FCRI was originally validated in a French-speaking sample of 600 patients with mixed cancers, and its English version was developed later.<sup>12</sup> The instrument had very good psychometric properties in previous studies.<sup>12,13</sup>

To our knowledge, scanty research has been conducted in the Iranian population regarding the fear of cancer recurrence, which might be tracked to the lack of appropriate measures. The purpose of this study was to develop a valid and reliable version of FCRI in Persian.

## Methods

### *Linguistic Validation*

The English version of FCRI was translated to Persian based on the standard guideline of the World Health Organization (WHO).<sup>14</sup> Accordingly, the English questionnaire was translated to Persian by two bilingual translators. After reaching a consensus regarding the translated Persian version, ten patients filled out the questionnaire, and words with unclear meaning were replaced and the final version was provided. An independent bilingual translator back-translated the final Persian version to English.

The content validity and equivalence testing were performed by five independent academic psychiatrists and a clinical psychologist. They rated the degree of the content covered by each item of the instrument, which is supposed to measure as an index for content validity. A five-point Likert scale was used in the ascending order for “appropriateness”

and “relevance” of the items.

### *Psychometric Evaluation*

#### *Participants*

Participants in this study were recruited from a breast cancer clinic affiliated to Tehran University of Medical Sciences (TUMS), and a private breast cancer clinic located in Tehran, Iran. Patients meeting the following criteria were included: The acceptable time period after the breast cancer treatment including surgery, radiation therapy and chemotherapy being six months to 5 years; absence of the objective evidence of recurrence; being fluent in the Persian language, and signing the informed consent. The protocol of the study was approved by the ethics committee of the Faculty of Medicine, Tehran University of Medical Sciences.

#### *Measures*

Fear of Cancer Recurrence Inventory (FCRI): The English version of FCRI has 42 items. FCRI is a multidimensional inventory developed by Simard *et al.* for use in all cancer patients. The questionnaire was originally validated in French-speaking patients with different cancers, and the English version was developed later by the same authors. The inventory evaluates seven aspects associated with FCR: the potential stimuli activating FCR (triggers; sample item: “Conversations about cancer or illness in general”); the presence and severity of intrusive thoughts associated with FCR (severity; sample item: “I believe it is normal to be worried or anxious about the possibility of cancer recurrence”); the emotional disturbance associated with FCR (psychological distress; sample item: “When I think about the possibility of cancer recurrence, I feel frustration, anger or outrage”); the impact of FCR on important areas of functioning (functioning impairments; sample item: “My thoughts or fears about the possibility of cancer recurrence disrupt my work or everyday activities”); the self-criticism toward FCR intensity (insight; sample item: “I feel that I worry excessively about the possibility of cancer recurrence”); the behavioral reassurance such as self-examination or repeated medical consultations (reassurance; sample item: “I call my doctor or other health professional to reassure myself”); and other strategies to cope with FCR (coping strategies; sample item: “I pray, meditate or do relaxation”).<sup>13</sup>

The Hospital Anxiety and Depression Scale (HADS): HADS is a brief and widely-used self-report questionnaire to determine the levels of anxiety and depression a person experiences. It is a fourteen-item scale. It has two subscales: HADS-A for anxiety and HADS-D for depression. Seven of the items are related to anxiety and seven are related to depression.<sup>15</sup> It has been translated and validated in many languages and it is widely used in the Persian



population for clinical and research purposes.<sup>1</sup>

#### Reliability Study

The Persian version of FCRI was tested for internal consistency through Cronbach's alpha coefficient for each domain and also for the whole questionnaire. A random sample of 60 patients was tested two weeks after the initial assessment. The intraclass correlation coefficient (ICC) was utilized for assessing the test-retest reliability of the questionnaire.

#### Validity Study

**Concurrent Validity:** In order to test the concurrent validity of the instrument, all participants completed the HADS questionnaire concurrent with the Persian version of FCRI, and the correlation of the scores of all questions was calculated.

**Construct Validity:** Factorial structure and dimensionality of the questionnaire were assessed through both principal component analysis (PCA) and confirmatory factor analysis (CFA).

#### Statistical analyses

For determining the degree of agreement between expert panel members in the second step of the translation process, a content validity index (CVI) was calculated. To assess the reliability of the Persian version of FCRI, Chronbach's alpha coefficient was assessed for internal consistency. Chronbach's alpha of greater than 0.7 was assumed satisfactory. For test-retest analysis, the intraclass correlation coefficient (ICC) was utilized. Principle component analysis (PCA) with oblique rotation was adopted for exploratory factor analysis. A Confirmatory factor analysis (CFA) with the parceling method was utilized as another way for assessing the dimensionality of the questionnaire.<sup>17</sup> Concurrent validity of FCRI was evaluated using correlations between the Persian version of FCRI subscale scores and HADS scores. A significance level of  $p \leq .05$  was assumed satisfactory. IBM SPSS-22 and AMOS-22 software were used for CFA.

## Results

### Linguistic Validation

The Persian version of FCRI was developed

based thoroughly on the previously-mentioned translation process. Each step was designed to improve the comprehensibility and acceptability of the questionnaire. There was no major cultural discrepancy between English and Persian versions.

A panel of experts examined content validity. The content validity index (CVI) for the seven subscales of the instrument (triggers, severity, psychological distress, functioning impairments, insight, reassurance and coping strategies) and total score of FCRI were 0.82, 0.84, 0.80, 0.85, 0.77, 0.79, 0.78 and 0.80 respectively. The Paucity of missing data in psychometric evaluation also confirmed the acceptability of the instrument.

### Psychometric Evaluation

A total of 450 patients with breast cancer participated in this study. The demographic characteristics of the subjects are summarized in Table 1. The mean age of the patients was 50.50 years (SD=9.75). Regarding the marital status of participants, 9.1% were single, 78.8% were married, 6.1% were widowed, and 6.1% were divorced. The descriptive statistics of different measures are also presented in Table 2.

### Reliability Study

Internal consistency was found to be acceptable with Cronbach's alpha coefficient at 0.86. The interclass correlation coefficient for test-retest reliability was between 0.87 and 0.99 (Table 3).

**Table 1.** Demographic characteristics of participant with breast cancer

Characteristics	Mean(SD)
Total number	450
Age (years)	50.50(9.75)
Education level (%)	
Illiterate	4.5
Elementary and junior high school	15.2
High School and Diploma	47
Higher education	33.3
Employment status (%)	
Housewife	57.6
Employed	21.2
Jobless	3
Retired	18.2

**Table 2.** Descriptive statistics of different measures in participants with breast cancer

Variables	Mean	Std. Deviation
Time passed from Diagnosis	29.16	14.15
Triggers	20.16	6.92
Severity	21.94	6.91
FCR		
Psychological Distress	8.91	4.31
Functional Impairment	12.79	5.96
Insight	5.78	3.01
Reassurance	7.24	2.90
Coping Strategies	27.89	8.27
Total Score	104.90	27.16
HADS		
HADS_A	6.63	4.42
HADS_D	4.92	3.84

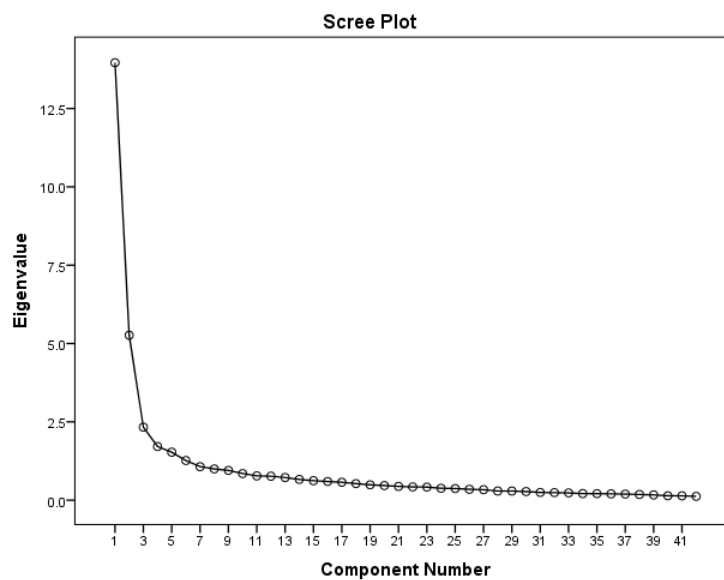
**Table 3.** Intraclass correlation coefficients (ICC) for test-retest of seven subscales and total scores of FCRI (N=60)

Items	ICC for test-retest	Lower Bound	Upper Bound	P Value
Trigger	0.87	0.72	0.94	0.001
Severity	0.76	0.47	0.89	0.001
Functional impairment	0.93	0.85	0.97	0.001
Insight	0.99	0.97	0.99	0.001
Reassurance	0.96	0.93	0.98	0.001
Coping Strategies	0.99	0.98	0.99	0.001
Total Score	0.96	0.93	0.98	0.001

**Table 4.** Pearson's correlation coefficient of the FCRI subscales scores and HADS subscales scores

	Triggers	Severity	Psychological Distress	Functional Impairment	Insight	Reassurance	Coping Strategies	FCRI-total
HADS-A	0.52*	0.59*	0.65*	0.55*	0.64*	0.24*	-0.04	0.59*
HADS-D	0.43*	0.45*	0.52*	0.51*	0.57*	0.14*	-0.15	0.45*

\* P&lt;0.05

**Figure 1.** The scree plot resulting from principle component analysis of the scores of the Persian version of FCRI

### Validity Study

Concurrent validity of FCRI was measured by Pearson's correlation coefficient between FCRI domains and scores of HADS. As it is shown in Table 4, except for the domain of coping strategies, all other six domains of FCRI, HADS-A, and HADS-D subscales were well correlated.

The principal component analysis revealed seven factors with eigenvalues of 13.96, 5.26, 2.33, 1.71, 1.53, 1.26, and 1.07, which accounted for 64.60 % of the variance observed (Figure 1). The factors extracted in this study were consistent with the domains of the original version of FCRI.

Based on the result of PCA, it is evident that the structure of the FCR could be explained better by a 7-factor solution. Also, to address sample size limitation to run CFA with 42 items, we ran a CFA with the parceling method. For a good model fit in CFA, sample size plays a notable role in the analysis. It gains more significance when researchers propose a complex model with a greater number of indicators

of a specific latent variable. The parceling method reduces the complexity of the proposed model by reducing the number of indicators. It has some advantages for CFA, including more reliability, meeting normality assumptions, satisfying sample size requirements, and better model fit indices.<sup>18,19</sup> In the parceling method, after computing item-scale correlation coefficients, two or three items would be summed creating a group under their subscale. Then, CFA would be run on these created groups rather than original items of the scale. The path diagram of CFA is presented in Figure 2. The goodness of fit measures is shown in Table 5 for CFA with 42 items and parceling methods. As illustrated in table 5, the goodness of fit measures was better in the parceling model than the original 42-item model. In the parceling model, RMSEA, CFI, IFI, PNFI, and PCFI showed acceptable goodness of fit, and GFI was nearly close to the acceptable value, i.e. 0.90. Meyers *et al* discussed the detailed information on the target values.<sup>20</sup> As previously mentioned, the parceling



method can help researchers to reduce the complexity of the model and address sample size limitation. Then, the results of the parceling model might imply that the sample size limitation in the present study leads to weaker model fit indices in CFA and there is no need to modify the hypothesized model of FCR.

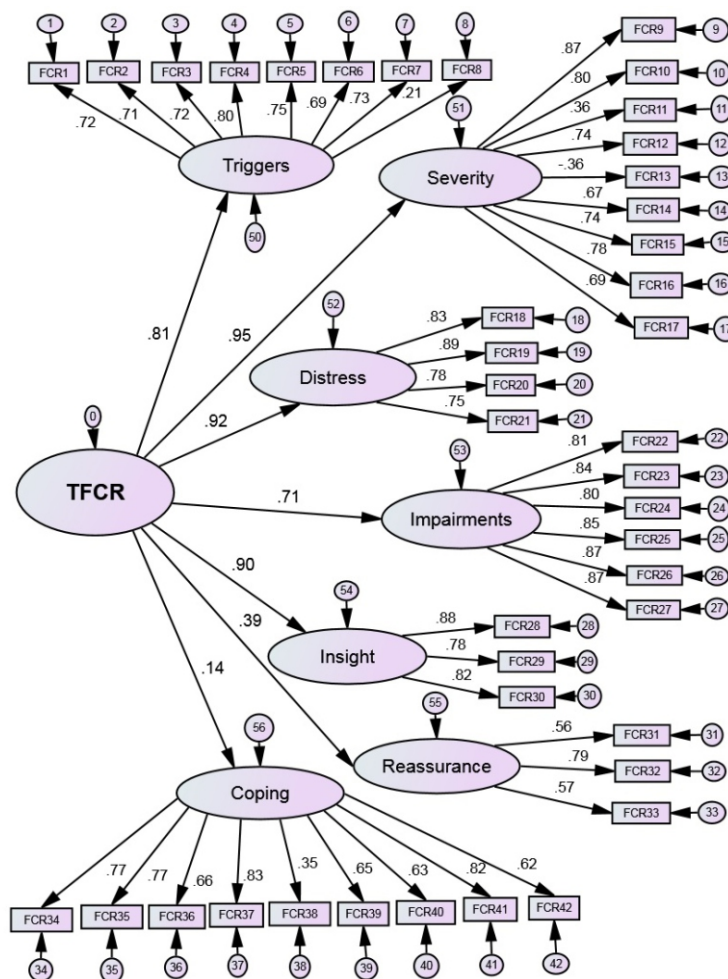
According to figure 2, the factor coefficients of the original hypothesized model (with 42 items) were assessed by AMOS 22 and the maximum likelihood estimation method. All of the factor coefficients were statistically significant at  $p < 0.05$ . The standardized regression weights ( $\beta$ ) of the Item-Subscale level for the 7-factor solution changed from 0.21 (item 8- Triggers) to 0.89 (item 19- Distress). The standardized regression weights of the Subscale-

FCR total Score level ranged from 0.14 (Coping) to 0.95 (Severity). The majority of standardized regression weights achieved meaningful significance ( $\beta > 0.3$ ). However, two Beta weights did not achieve meaningful significance criterion, including item 8 (0.21) and the Coping subscale (0.14). Then, it might be proposed to modify the hypothesized model to achieve a stronger model for the FCR. It is also notable to mention that the Beta weight of the subscale level in the parceling model ranged from 0.21 (coping) to 0.95 (severity). The Beta weight of the coping subscale increased from 0.14 to 0.21, respectively, in original and parceling models. It might be considered that sample size limitation could explain the weak results of the original model.

**Table 5.** Goodness of fit measures of the confirmatory factor analysis with a grouping method for the Persian version of FCRI

Model	Chi-Square	DF, p-value	GFI	RMSEA	CFI	IFI	PNFI	PCFI
42 items	2846.3	812, $P < 0.001$	0.73	0.08	0.82	0.83	0.73	0.78
parceling	641.4	182, $P < 0.001$	0.87	0.08	0.92	0.92	0.78	0.79

Note: GFI= goodness of fit index; RMSEA= root mean square error of approximation; CFI= comparative fit index; IFI= Incremental Fit Index; PNFI= parsimonious normed fit index; PCFI= parsimonious CFI.



**Figure 2.** Path diagram of confirmatory factor analysis for the Persian version of FCRI



## Discussion

This study aimed to develop a Persian version of FCRI and to assess its reliability and validity. It was accomplished through standard forward-backward guidelines. The final version of the questionnaire was obtained after face and content validation. The FCRI was comprehensible and easily applicable to the patients. Content validity indices of total and specific domains of the questionnaire were robust. According to Lynn, with six or more judges, the CVI should not be lower than 0.78 for an item to be judged acceptable.<sup>21</sup> The Cronbach's alpha for the whole questionnaire that provides an estimate of internal reliability was 0.86, which is high and satisfactory. Test-retest reliability was 0.96 over two weeks using ICC, which shows the high stability of FCRI over time. Correlations between the FCRI and HADS were remarkable ( $r= 0.252$  to  $0.639$ ), indicating acceptable concurrent validity. As expected, there was a negative correlation between HADS subscale score and coping strategies subscale score of FCRI. In other words, higher scores in coping strategies imply the fact that patients have better ways to deal with their fear of cancer recurrence and the lower possibility of depression and anxiety.

A similar value was found by Lebel *et al.* while assessing 350 English-speaking patients with different cancer types. In that study, the English version had high internal consistency (0.96 for the total scale and 0.71–0.94 for the subscales) and test-retest reliability (0.88 for the total scale and 0.56–0.87 for the subscales).<sup>13</sup> In the original study conducted by Simard *et al.*, they evaluated 600 French-Canadian patients who had been survivors of breast, prostate, lung, and colorectal cancer. Results supported the internal consistency ( $\alpha=0.95$ ) and the temporal stability ( $r=0.89$ ) of FCRI, as well as its construct validity with other self-report scales assessing the fear of cancer recurrence ( $r=0.68$  to  $0.77$ ) or related constructs such as psychological distress ( $r=0.43$  to  $0.77$ ), and quality of life ( $r= 0.20$  to  $0.36$ ).<sup>12</sup>

Factor analysis using principal component analysis (PCA) revealed seven-factor solutions for this questionnaire. This finding is similar to seven dimensions of the original French questionnaire and the English version of FCRI.<sup>13,14</sup> Confirmatory factor analysis, along with parceling method, illustrated an acceptable fit of the factor structure of the FCR. However, the sample size limitation could explain the weak goodness of fit measures for CFA with 42 items.

The current study has various limitations that should be considered in the interpretation of the results. First, the sample size of the study may not be ideal for confirmatory factor analysis. Second, due to the lack of another validated instrument for the evaluation of FCR, only the HADS questionnaire was used for the assessment of concurrent validity of the Persian version of FCRI.

In conclusion, the Persian version of FCRI is a reliable and valid measure and can be used for the assessment of the fear of cancer recurrence in patients with breast cancer. It can assist clinicians to have a multidimensional view of the fear of cancer recurrence and can be used for both clinical and research purposes. We recommend that the Persian version of FCRI is employed in populations with different types of cancer and that its sensitivity to change be assessed.

## Conflict of Interests:

There is no conflict of interest to declare to do in this study.

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