

Original Article

Fear of Cancer Recurrence 7 Scale Tamil Translation and Validation among Breast Cancer Survivors in India

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ABSTRACT

Objectives: Fear of cancer recurrence (FCR) is one of the most widely reported conditions among cancer survivors. The present study aims to translate and validate FCR7 scale into regional language tamil among breast cancer survivors (BCSv).

Material and Methods: A cross-sectional study comprising a sample of 106 breast cancer survivors was carried out. FCR 7 scale, functional assessment of cancer therapy-B (FACT-B) and impact of event scale-R (IES-R) were used for establishing reliability and validity. Translation of the FCR7-T scale was done from English into Tamil following the international guidelines and a field study was performed.

Results: The test-retest reliability was established for FCR 7 Tamil with a Cronbach's alpha of 0.96 and ICC value of 0.910. On Spearman's correlation, an inverse relationship was found between FCR7 and FACT-B ($r = -0.259$ and $P = 0.01$). The survivors with high FCR reported poorer quality of life.

Conclusion: The Tamil version of the FCR7 tool is highly sensitive for measuring FCR.

Keywords: Breast cancer survivors, Fear of cancer recurrence, India, Translation, Validation study

INTRODUCTION

Fear of cancer recurrence (FCR) is a common concern and applies to patients with cancer irrespective of their cancer site. It is a normal reaction to a life-changing event.^[1]

One of the most relevant definitions of FCR is 'the fear or worry that cancer could return or progress in the same place or another part of the body.'^[2] The most prevalent and top concerned unmet need reported was FCR, but the level of FCR stated by the survivors varied between low and moderate. Few psychosocial factors associated with higher FCR were younger age, comorbid physical symptoms and their severity, mental distress and poorer quality of life. The aftermath of FCR affected patients' behavioural, emotional and functional aspects.^[3]

The assessment of FCR is crucial for understanding the psychological state of a patient's diagnosis and treatment. There are various measures available for assessing FCR, a few of the most popularly used are listed as Cancer Worry Scale,^[4,5] FCR Inventory (FCRI),^[6] Concerns about

Recurrence Questionnaire-4,^[7] fears of cancer recurrence scale (FCR7) and short-form (FCR4).^[8]

FCR7 is one of the most widely used, comprehensive and simple tools. This scale was translated and validated into Chinese among early-stage lung cancer patients. Findings indicated that FCR7 C was a brief and psychometrically valid tool that was strongly recommended for screening among Chinese-speaking cancer patients for baseline assessment and management.^[9]

While analysing the literature on FCR, shows that the majority of FCR-related studies have taken place in developed countries. The primary reason for this contrast is that FCR being a relatively new phenomenon under study is slowly gaining significance and popularity within the medical fraternity. The lack of standardised tools in the regional languages may have contributed to less research on FCR from lower- and middle-income countries.

A screening tool to assess the FCR in any regional Indian language was unavailable; hence, there was a need to translate

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and validate the FCR7. Therefore, the present study aims to translate and validate the FCR7 scale into the regional language Tamil.

Ethical statement

This research work is a part of the work approved by the Institute Ethical Committee (IEC), Cancer Institute (WIA), Chennai, Ref no: IEC/2020/16 September. A signed written consent form was obtained from all participants of the study. The patients were allowed to withdraw at any time.

MATERIAL AND METHODS

Sample

A cross-sectional study was conducted among breast cancer survivors (BCSv) between 20 and 64 years at the outpatient department. The total number of follow-up patients of all age groups who visited the breast cancer unit from October 2020 to January 2021 was 7881. From the total number of follow-up patients, the sample for this study was recruited based on the inclusion criteria. The inclusion criteria comprised of BCSv speaking the native language (Tamil) who have completed treatment with curative intent and are considered disease-free for a minimum period of 3 months. A minimum grade of 7th standard education, histopathologically proven breast cancer Stages I–III (curative) and who had undergone multimodality treatment were considered. Participants with a history of psychiatric illness and currently under antipsychotic medication were excluded from this study. The eligible BCSv were briefed about the research purpose before recruitment.

Translation procedure

The FCR7 author was contacted and permission for the translation was sought. The translation and cross-cultural adaptation and validation were carried out using the forward and backward protocol by adopting the international guidelines.^[10] Two independent experts who were native speakers of the target language and proficient in English translated FCR 7 from the original language English to the target language Tamil (Forward translation Tamil I and II). Reconciliation processes were carried out for both the forward translated Tamil versions. The most meaningful and culturally appropriate words were chosen to decide on the final reconciliation version FCR 7 Tamil I. This reconciliation version was back-translated by two independent experts to source language (back translation I and II) to confirm any ambiguous statements and discrepancies. Thus, framing the back-translated report constitutes two forward translations, one reconciliation report and two backward translations. Proofreading of the FCR 7 Tamil version was carried out to rectify any mistakes in the language or any other faults. A field study was conducted and concluded by finalising the FCR 7 Tamil scale (FCR7-T) [Figure 1].

The content validity of the study could be established when the FCR7 scale was provided to the subject matter experts and were asked to provide their feedback on how accurately each of the questions depicted the construct in question. The feedback received from them was matching with the responses of the original FCR7 scale. The first four questions reflected anxiety related to the FCR, questions 5 and 7 represented impaired cognitive process subsequent to anxiety and 6th question depicted behavioural responses. These factors were considered effective in the FCR7 questionnaire. The translated version of the FCR7-T scale was face validated by administering to 10 BCSv. The BCSv was asked whether all the questions were understandable and sounded natural and whether the sentence construction was relevant to the context. BCSv were also enquired about any words they felt were irrelevant or out of context concerning FCR, and their suggestions were recorded. Subsequently, test and retest analysis was carried out on 38 BCSv from the same setting with the inclusion criteria stated earlier, out of which 32 responded for a retest with a time interval of 15 days. After the test-retest reliability, internal consistency reliability (Cronbach's alpha) was established with 106 BCSv following the same recruitment criteria. To better understand the item – quality of FCR7-T, we did item to total (scale) correlation.

Instruments

FCR7 is a 7-item brief unidimensional scale; the first four items constitute the FCR4 scale along with additional three items to measure FCR directly. The first four questions of the FCR7 scale depict anxiety and worry about cancer recurrence. Questions 5 and 7 represent the distorted cognitive processes consequent to anxiety or worry. Finally, observable reaction/behavioural response is measured with question 6, making this scale, the most precise, simple, efficient and effective tool to screen and assess FCR in a busy clinical setup. FCR7 is a self-administered seven-item scale to assess the FCR. The response pattern for the first six items was on a 5-point scale ranging from 1 indicating 'not at all' to 5 displaying 'all the time'. Only the seventh item alone is on a 10-point rating from 0 denoting 'not at all' to 10 markings 'a great deal'. The total score ranges from 0 to 40, with a higher score indicating a higher level of FCR.^[8,9]

Impact of event scale R (IES-R) is one of the most widely used self-report measures and was originally validated in English, which was later on translated to many languages, including Tamil by Russell *et al.*^[11]

The functional assessment of cancer therapy-breast (FACT-B) was initially developed in English. It is a 37-item instrument designed to measure five domains of Health-related quality of life (HRQOL) in breast cancer patients.^[12]

Statistical analysis

All analyses were carried out using the Statistical Package for the Social Sciences. Descriptive statistics, including frequency

and percentage for the patient characteristics and clinical profile, were calculated. The internal consistency (Cronbach's alpha coefficient) and interclass coefficient were measured to assess the test-retest reliability of the FCR7 T scale. An item to total correlation and Cronbach's alpha was calculated to examine item quality. FCR7 total with each item rank correlation was carried out at 0.01 level to assess the pattern of relationship that is if it has a weak or strong correlation. Spearman rank correlation between FCR7 T and FACT-B and IES-R was carried out to establish convergent and divergent validity. Spearman's rank correlation between items was done to examine the strength and direction (negative/positive) of a relationship between items. To establish criterion validity, the FCR7 scale was compared with FACT-B and IES-R.

For assessing the severity of FCR, a median score was taken and the percentage above and below the median was calculated.

RESULTS

Participants reported their FCR during face validity and expressed that the items were easy to comprehend and respond to. Hence, FCR7-T was well supported by the BCSv. Subsequently, a field study was carried out on a sample of 32 BCSv [Supplementary Table 1] with a mean age of 50.25 (SD7.94). The interclass correlation coefficient (ICC) for test and retest was 0.910 with a range of 0.816–0.956 which shows excellent internal consistency and a Cronbach's alpha of 0.962 value indicating high reliability for FCR7-T. Given that Cronbach's alpha is 0.96 and ICC value of 0.910, test-retest reliability was established for FCR 7 Tamil.

Following the establishment of test-retest reliability, the FCR7-T was validated with a sample of 106 consecutive BCSv.

All BCSv were females, with the exclusion of three cases as they did not meet the inclusion criteria. Hence, a total of 106 BCSv were considered for final analysis [Table 1]. The mean age of 106 samples was 46.58 (SD 8.9) years. The majority of the survivors received a school education and 40.6% of BCSv were between 40 and 50 years.

An equal representation was reported on the place of stay of the BCSv; however, most of them stayed in metropolitan cities (40.6%). More than two-thirds of the samples were Hindus (90.6%), and the majority of them were married (83%), with 75.5% belonging to the nuclear family and 87.7% comprised homemakers. On the duration of survivorship, a larger portion of BCSv (38.7%) belonged to <2 years after the completion of treatment. More than half of BCSv was diagnosed with Stage II breast cancer (67.9%) [Table 1].

In all invasive breast cancer survivors, a large portion of BCSv was treated with mastectomy (88.7%) and chemotherapy recipients were 93.4%. Two-thirds of the BCSv were treated with radiotherapy (67%) and hormonal therapy (75.5%). The majority of the samples were identified to be positive with the

Table 1: Demographic and clinical characteristics of the study population (n=106).

Variables	Frequency	Percentage
Age (mean±SD)	46.58 (8.9)	
Range	24–64	
Age category (years)		
24–39	26	24.5
40–50	43	40.6
51–64	37	34.9
Education		
School	83	78.3
College	23	21.7
Place of stay		
Village	38	35.8
Town	25	23.6
Metropolitan	43	40.6
Religion		
Hindu	96	90.6
Christian	8	7.5
Muslim	2	1.9
Marital status		
Single	5	4.7
Married	88	83
Widow/separate	13	12.3
Duration of survivorship (years)		
<2	41	38.7
2–5	34	32.1
>5	31	29.2
Family type		
Joint	26	24.5
Nuclear	80	75.5
Occupation		
Employed	13	12.3
Homemaker	93	87.7
Tumour stage		
Stage I	1	9
Stage II	72	67.9
Stage III	33	31.1
Tumour marker oestrogen		
Positive	84	79.2
Negative	20	18.9
Not available	2	1.9
Tumour marker progesterone		
Positive	61	57.5
Negative	42	39.6
Not available	3	2.8
Tumour marker Her 2		
Positive	58	54.7
Negative	42	39.6
Not available	6	5.7
Surgery		
MRM	94	88.7
BCS	12	11.35
Chemotherapy		
Received	99	93.4
Not received	7	6.6

(Contd...)

Table 1: (Continued).

Variables	Frequency	Percentage
Radiotherapy		
Received	71	67
Not received	35	33
Hormonal therapy		
Received	80	75.5
Not received	26	24.5
Comorbidity		
No comorbidity	59	55.7
Diabetic	11	10.4
Blood pressure	12	11.3
Hypothyroidism	9	8.5
Other medical comorbidities	2	1.9
Two or more commodities	13	12.3

SD: Standard deviation

tumour markers oestrogen (79.2%). Around half of the BCSv did not have any comorbidity [Table 1].

A few missing items were found in hormone receptors and Human Epidermal Growth Factor Receptor 2 (HER2) where the details were unknown.

The internal consistency of FCR7-T using Cronbach's alpha was found to be 0.864 for 106 BCSv indicating high internal consistency for the tool.

An item to total score (scale) correlation of FCR7 T was conducted to better understand item quality. In the present study, item to total correlation ranged between 0.568 and 0.940, which comes under the acceptable level of alpha; hence, we kept all the original items of FCR7. While comparing the internal consistency (Cronbach's alpha value of 0.864) ($n = 106$) of FCR7-T with each item-total correlation comparatively, the weakest relation was found with Item 6 (0.568) followed by Item 5 (0.761), which was preceded with Item 4 (0.839), Item 2 (0.826) and Item 3 (0.818). The most robust relationship with the Cronbach's value of 0.96 was found with Item 7 (0.940) and Item 1 (0.873) [Table 2].

The results of correlation indicated that all items had a significantly strong correlation between them at a 0.01 level except Item F6 (0.616) [Table 3].

[Table 4] shows that a relationship could be established with FCR7 and both scales FACT-B and IES-R. On FACT-B ($r = -0.259$ and $P = 0.01$), the survivors with high FCR reported poorer quality of life and with IES-R ($r = 0.270$ and $P = 0.01$), the correlation value was found significant at $P = 0.01$ level. While considering the critical value for Spearman's table (according to the method by Kendall and Smith, 1939), the value is 0.197 at a 0.05 level for the sample size of 106. The results are greater than the critical value of 0.197, establishing criteria validity for the FCR7 scale.

A Chi-square analysis was conducted to assess the association of FCR7 with the demographic and clinical characteristics, but no significant association was found.

Table 2: Internal consistency reliability and item to total correlation ($n=106$).

FCR item	Item to total correlation	Alpha if item deleted
F1 I am afraid that my cancer may recur	0.873	0.750
F2 I am worried or anxious about the possibility of cancer recurrence	0.826	0.764
F3 How often have you worried about the possibility of getting cancer again	0.818	0.765
F4 I get waves of strong feelings about cancer coming back	0.839	0.767
F5 I think about cancer returning when I did not mean to	0.761	0.768
F6 I examine myself to see if I have physical signs of cancer	0.568	0.773
F7 To what extent does worry about getting cancer again spillover or intrude on your thoughts and activities	0.940	0.678

Overall Cronbach's alpha=0.864

To measure the severity of the FCR, the median was calculated as 17 and 51.9% of breast cancer survivors reported less FCR than the median value, and a balance of 48.1% was observed to have higher FCR than the median [Figure 2].

DISCUSSION

As far as the available literature is considered, this is the first study to explore and establish reliability and validity on FCR7 scale in any regional language in India. The present study was exclusively carried out among a homogeneous group of breast cancer survivors. This scale was originally validated in English.^[8] In the present study, a few participants who were emotionally affected during the administration of the tool were provided with professional support by the researcher who is a trained clinical psychologist.

From the study results, the FCR7-T version was found to be highly reliable with strong internal consistency, reliability and satisfactory criterion validity.

A strong correlation was found between each item-total correlation and internal consistency value. The present study found the lowest correlation with FCR Item 6 and the highest correlation with FCR Item 7. These results exactly replicated the lowest and highest scores and supported the psychometrics exploratory factor analysis in the original study.^[8] The item-total correlation is in line with the French-Canadian version item-total correlation of the FCRI study.^[6]

Table 3: Spearman's rank correlation between scores.

FCR7 questionnaire	F1	F2	F3	F4	F5	F6	F7	FCR7 total
F1 – I am afraid that my cancer may recur	1	0.696** (0.001)	0.773** (0.001)	0.752** (0.001)	0.622** (0.001)	0.449** (0.001)	0.895** (0.001)	0.887** (0.001)
F2 – I am worried or anxious about the possibility of cancer recurrence		1	0.835** (0.001)	0.797** (0.001)	0.716** (0.001)	0.414** (0.001)	0.782** (0.001)	0.851** (0.001)
F3 – How often have you worried about the possibility of getting cancer again			1	0.821** (0.001)	0.691** (0.001)	0.386** (0.001)	0.786** (0.001)	0.866** (0.001)
F4 – I get waves of strong feelings about the cancer coming back				1	0.772** (0.001)	0.469** (0.001)	0.783** (0.001)	0.874** (0.001)
F5 – I think about the cancer returning when I did not mean to					1	0.389** (0.001)	0.728** (0.001)	0.806** (0.001)
F6 – I examine myself to see if I have physical signs of cancer						1	0.564** (0.001)	0.616** (0.001)
F7 – To what extent does worry about getting cancer again spillover or intrude on your thoughts and activities							1	0.961** (0.001)
FCR7 total								1

**Correlation is significant at the 0.01 level (two-tailed)

Table 4: Spearman's rank correlation between FCR 7, FACT-B and IES R.

Scales	FCR 7 (total)	FACT-B (total)	IES-R (total)
r	1	-0.259** (0.007)	0.270** (0.005)

**Spearman's rho correlation is significant at the 0.01 level (two-tailed)

In the results item-total scores with each item scores and between items, the lowest agreement was found with Item F6, 'I examine myself to see if I have physical signs of cancer'. This may be because this particular question focuses on self-examination, which comes under the routine screening practises and is mostly advised by the physicians to patients. Hence, it stands independent from the rest of the questions in FCR7 that is irrespective of whether the patients experiencing FCR or not they follow the self-examination process.

FCR7 – 6th question alone has a physical assessment which is not a direct question on FCR, which is stated in the study conducted on lung cancer patients FCR and hence may be one of the factors justifying the Item 6th of FCR having a weak correlation with the total item.^[9]

Results depicted a monotonic relationship of FCR 7 with FACT-B and IES-R. An inverse correlation between FCR and quality of life (FACT-B) states that breast cancer survivors with high FCR experienced a poorer overall quality of life. Our results replicated studies done by Shin *et al.*^[13] who also concluded an inverse correlation between FCR and European Organisation for Research and Treatment of Cancer (EORTC) Core Quality of Life questionnaire (QLQ-C30) on QoL indicated that cancer patients with high FCR might have a poor quality of life.

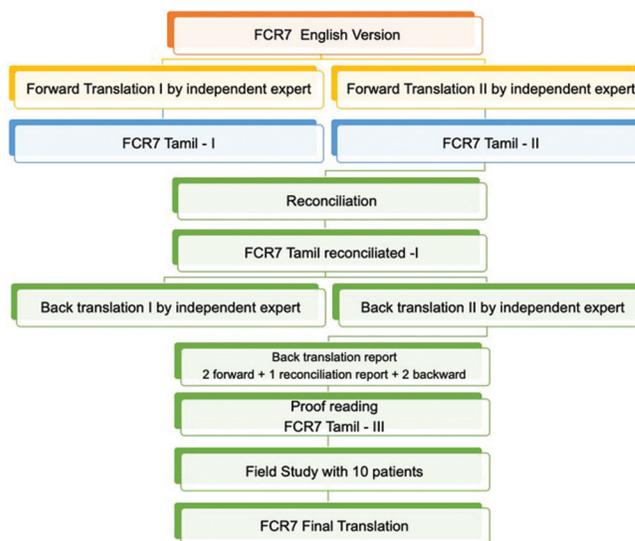


Figure 1: The process followed for FCR7 translation.

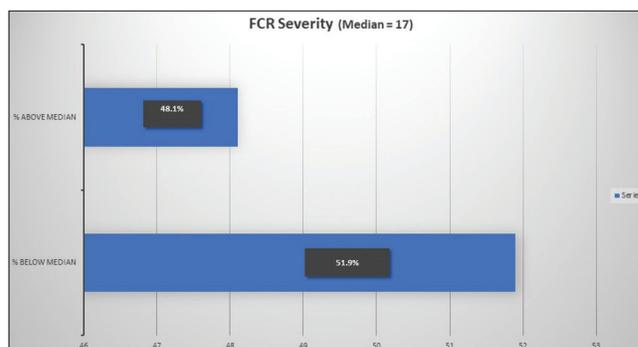


Figure 2: FCR median and percentage of BCSv falling below and above the median.

FCR7 T had a positive correlation with IES-R stating that survivors with higher FCR had symptoms such as intrusive thoughts about cancer coming back and anxiety features, which may be included in the hyperarousal subscale combinedly reflecting post-traumatic stress symptoms in the participants. These observations were similar to the findings of Mehnert's study on fear of cancer progression (FoP) and cancer-related intrusive cognitions in breast cancer survivors. Significant correlations were noted between FoP and post-traumatic stress disorder diagnosis.^[14]

While considering the median of FCR, it was found that around half of the BCSv experienced more FCR during their survivorship period, which is similar to the studies by Schapira *et al.*^[15] where it was reported that the majority of the population had reported moderate to high FCR, however, which was fluctuating over a while.

Study limitation

This study was conducted during the COVID-19 pandemic period; however, there was no lockdown during the data collection phase in India. The pandemic effect would have had its implication on the responses provided by the breast cancer survivors. The study was conducted on a homogeneous group and participants with minimal education were only recruited.

Clinical and research implication

FCR7 scale can be translated and validated into other regional languages in India. It is a short tool that could be used in a busy clinical setting and may be integrated into the survivorship assessment plans. FCR is in its nascent stage in India and, hence, the future research can focus on three key areas: (1) Better assessment of FCR throughout the continuum of survivorship and its relation with other cancer survivors' symptoms, (2) risk factors and management of FCR and (3) research on underdiagnosed and untreated FCR and its patterns of fluctuation.

CONCLUSION

The Tamil version of the FCR7 tool is highly sensitive for measuring FCR.

The results of FCR7 T reveal that it is a brief, valid and reliable tool for assessing cancer recurrence. FCR is primarily applicable to the survivor group, and FCR7 T emerged as a sensitive tool. Their worry about cancer recurrence could be measured appropriately.

Recommendations

A more divergent cancer survivor population would have given a better perspective of the fear of recurrence in other malignancies. A cutoff score for the FCR7 scale would be more psychometrically beneficial.

Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Supplementary Table 1: Demographic and Clinical characteristics of the study population (N=32)

Participants Characteristics	Frequency	Percentage
Place of stay		
Village	11	34.4
Town	12	37.5
Metro	9	28.1
Religion		
Hindu	27	84.4
Christian	5	15.6
Gender		
Female	32	100
Marital Status		
Married	32	100
Educational Status		
Less than college graduation	22	68.8
College Graduate	10	31.5
Occupation		
Employed	9	28.1
Home maker	23	71.9
Family type		
Joint family	10	31.3
Nuclear family	22	68.8
Duration of survivorship		
< 2 years	13	40.6
2 – 5 years	9	28.1
More than 5 years	10	31.3
Tumour stage		
Stage I	1	3.1
Stage II	18	56.3
Stage III	13	40.6
Tumour marker ER		
Positive	24	75.0
Negative	7	21.9
Not available	1	3.1
Tumour marker PgR		
Positive	20	62.5
Negative	11	34.4
Not available	1	3.1
Tumour marker Her2		
Positive	23	71.9
Negative	7	21.9
Not available	2	6.3
Diabetics		
Yes	11	34.4
No	21	65.6
B.P		
Yes	6	18.8
No	26	81.3
	Mean	SD
Age	50.25	7.94

Cronbach's Alpha=0.962