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Fear of Cancer Recurrence Inventory: development and initial validation of a multidimensional measure of fear of cancer recurrence

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Abstract
Background Despite the fact that the fear of cancer recurrence is to varying degrees almost universal in cancer survivors, there is a lack of validated multidimensional instruments to evaluate this issue specifically.
Purpose The goal of this study was to develop and empirically validate a multidimensional self-report scale for assessing the fear of cancer recurrence, the Fear of Cancer Recurrence Inventory (FCRI).
Methods A provincial medical databank was used to randomly select a pool of 1,704 French-Canadian patients who had been treated for breast, prostate, lung, and colorectal cancer within the past 10 years. Of these, 300 patients were asked to complete the FCRI on two occasions.
Results The factorial analysis conducted on the final 42-item scale revealed a seven-component solution (64% of the variance) including the following factors: triggers, severity, psychological distress, coping strategies, functioning impairments, insight, and reassurance. The results also supported the internal consistency (α=0.95) and the temporal stability (r=0.89) of the FCRI, as well as its construct validity with other self-report scales assessing 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).
Conclusions This study suggests that the French-Canadian version of the FCRI is a reliable and valid instrument for evaluating the multidimensional aspects of the fear of cancer recurrence.

Keywords Fear of cancer recurrence · Anxiety · Cancer · Questionnaire · Validation

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Introduction

Improved methods of cancer detection and treatment have led to rising numbers of patients surviving and living with the disease for prolonged periods of time. It is estimated that 833,100 and 10.5 million cancer survivors are currently living in Canada and in the USA, representing 2.6% of the Canadian [31] and 3.6% of the American population, respectively [34]. As more people survive cancer, greater attention is being given to the quality-of-life issues and how individuals adapt to this chronic disease.

The fear of cancer recurrence (FCR) is believed to be very common in cancer survivors, almost universal to varying degrees, and it is thought to persist long after the termination of cancer treatments [11, 20, 25, 27, 32, 42, 43]. To our knowledge, there is no definition of FCR that is widely accepted. In this study, we used the broad definition of FCR adopted by Vickberg et al. [41]: the fear or worry that the cancer will return or progress in the same organ or in another part of the body. Previous studies, mostly conducted in breast cancer patients have indicated that 22% to 99% of cancer survivors report FCR [20, 24, 25, 29, 33, 41, 44]. In a recently published study, FCR was the first or second most commonly reported problem by patients

with breast, colorectal, lung, or prostate cancer [4]. More specifically, the proportion of cancer survivors reporting FCR was found to range from as high as 74% in lung cancer survivors to 49% in prostate cancer survivors. In another recent study conducted in 1721 cancer patients with mixed cancer sites and tumor stages, the most distressful problem reported was the fear of disease progression or recurrence [17].

Several factors have been found to be associated with FCR. Among demographic characteristics, a younger age, the female gender, and a higher level of education have all been found to be associated with greater levels of FCR [13, 25, 38, 41]. With regard to medical characteristics, a shorter time elapsed since cancer diagnosis, the administration of more aggressive cancer treatments (e.g., chemotherapy), and cancer progression (e.g., localized and metastatic recurrence) [21, 25, 30] have been found to be associated with FCR, although controversial findings have also been obtained [24, 25, 38].

Although FCR has consistently been identified in anecdotal reports or general quality of life studies as a common problem with several negative consequences, including psychological distress [38, 41] and functioning impairments [39], there have been few systematic studies on this issue [5, 25]. This may be at least partly explained by the complexity of the phenomenon and the lack of a standardized assessment method that would allow an adequate evaluation of the multidimensional manifestations of FCR and a comparison of data across studies.

There are a few brief tools available to assess FCR. The *Fear of Recurrence Index* [23], a two-item scale, evaluates the patients' own concerns and their perception of their family's concerns over the reappearance of disease. The *Worry about Cancer Scale* [10], a four-item scale evaluates triggers that influence worry, perceived risk, and distress about the possibility of a cancer recurrence. The *Fear of Recurrence Scale* [15] is a five-item scale assessing beliefs and anxiety about a possible recurrence. Finally, the *Assessment of Survivor Concerns* [14], a six-item scale measures fears about recurrence and health in cancer patients. However, only a few psychometric properties are available on those short scales, reflecting only a limited number of dimensions associated with FCR.

Three more extensive questionnaires have also been developed to assess FCR. The *Fear of Recurrence Questionnaire* (FRQ) [32] was the first to be specifically developed to assess FCR. This 22-item questionnaire evaluates worry about health status and illness returning, triggers that influence worry, uncertainty, and the concerns of significant others. Although this questionnaire has been shown to have adequate reliability [18], its validity has not been investigated, and FCR was considered unidimensional. The *Concerns About Recurrence Scale* (CARS) [41] is a 30-item scale that evaluates overall FCR (e.g., frequency, duration, severity) and the specific nature of women's fears about breast cancer recurrence. Preliminary evidence of its reliability and validity is available, but the CARS had been developed to be used specifically in breast cancer patients. The *Fear of Progression Questionnaire* (FoP-Q) [16] is a 43-item scale evaluating five dimensions of fear of progression (i.e., affective reactions, partnership/family, occupation, loss of autonomy, and coping strategies for anxiety) of three chronic illnesses (i.e., cancer, diabetes mellitus, and rheumatoid disease). This questionnaire has shown adequate psychometric properties with regard to the total sample, but no separate analysis was conducted only for cancer patients. Also, it contains no item to assess the frequency and duration of FCR, which have been identified in the literature on anxiety disorders as important dimensions to distinguish between normal concerns of a real threat from an irrational or excessive fear [8].

In short, there are some self-report scales available to assess various characteristics of FCR. However, they were developed to be used only with breast cancer patients or have not been fully validated. Moreover, none of them was developed with the objective of evaluating all the relevant dimensions of FCR. For instance, it appears crucial that the coping strategies used by the patients should be taken into account to better distinguish patients who have no FCR at all from those who report no FCR on a severity scale because they use a great deal of avoidance strategies that could lead to significant psychological distress and, eventually, to a lower adherence to medical care and poorer medical outcomes. It also appears important to assess components such as intrusive thoughts and functioning impairments associated with FCR to better identify patients who would need professional intervention to help them cope more effectively with the uncertainty associated with cancer.

The goals of the present study were to develop and to evaluate the initial psychometric properties of a new multidimensional self-report scale assessing FCR, the *Fear of Cancer Recurrence Inventory* (FCRI), in a group of cancer patients who were heterogeneous in terms of cancer sites, stages, and time elapsed since their cancer diagnosis.

Materials and methods

Development of the FCRI

Two meetings (90 min) were first held with six experts in psycho-oncology (i.e., three psychologists, two psychiatrists, and one nurse). During the first meeting, the committee was invited to provide answers to the following questions: (a) What is the best definition of FCR?; (b) What

makes FCR a normal reaction or a pathological condition?; (c) Based on your clinical experience, what are the manifestations and the consequences of FCR (i.e., behavioral, emotional, physiological, and cognitive)?; (d) What constructs should be found in an FCR questionnaire?; and (e) What kind of items should be included in such a questionnaire? An initial French-Canadian version of the FCRI was then prepared by the authors based on the suggestions of the committee of experts and the information collected in the literature on FCR and anxiety disorders. Some items were adapted from those included in available FCR questionnaires [10, 15, 32, 41] and in the Cognitive Intrusive Questionnaire [12]. During the second meeting, the committee was invited to comment on the format of the initial version of the FCRI (which contained 75 items), the instructions for patients, and the relevance and formulation of each item.

In accordance with previous work [41], the committee of experts agreed to use a more inclusive definition of FCR. Thus, FCR was defined as the fear or worry of the possibility that the cancer will return or progress in the same organ or in another part of the body. Although this definition of cancer recurrence is not as precise as the one used by cancer care providers, it better reflects how recurrence is generally conceived by patients themselves. In addition, efforts were made to include items reflecting a cognitive–behavioral conceptualization of FCR inspired by the model developed by Lee-Jones et al. [25]. Furthermore, some items were inspired by certain DSM-IV diagnostic criteria [2] of anxiety and somatoform disorders (e.g., triggers, severity of fear, functioning impairments, self-criticism, and coping strategies including avoidance and reassurance strategies) to better assess the clinical significance of self-reported FCR.

Pilot study

The initial French-Canadian version of the FCRI was tested in ten cancer survivors (e.g., four breast, three prostate, two lung, and one colorectal; 60% were female, and 50% had had a cancer recurrence) who had received treatment at the hospital L'Hôtel-Dieu de Québec (L'HDQ). Initially, the participants were asked to complete the FCRI. They were then interviewed on the clarity of the instructions, the appropriate format of the questions and possible answers, the content, and their reactivity, if any, to the measure. They were asked to provide alternative formulations for items that were found to be unclear and to suggest additional items, which would be appropriate.

Overall, the participants were able to identify correctly the general content being measured by the questionnaire (i.e., good face validity), and they agreed on the definition of "cancer recurrence" provided in the instructions. The questionnaire was considered to be clear, and only some items (n=10) required reformulation to make them more easily understandable. Only two additional items were suggested for inclusion in the questionnaire. The participants reported that the time and the effort needed to complete the FCRI were reasonable. The questionnaire was found to be somewhat distressful by a few participants, but they specified that this reaction was only momentary and would not have prevented them from completing it if they had received it by mail.

Participants

A provincial databank from the *Régie d'assurance maladie du Québec* (RAMQ) was used to randomly select a large pool of patients who had been treated for cancer at the hospital L'HDQ, Québec, Canada, while respecting proportions equivalent to Canadian statistics on cancer prevalence [31]. Inclusion criteria were: (a) participants had had a medical visit in oncology at L'HDQ within the past 5 years; (b) had been treated for breast, prostate, lung, or colorectal cancer within the past 10 years; (c) were younger than 80 years of age to avoid including patients with severe cognitive deficits; and (d) were able to read and understand French. Among the 1,704 patients who were invited to participate in the study by mail, 1,155 (68%) responded. Of this number, 355 (31%) refused to participate and 55 (5%) of the mailing packages were returned uncompleted because of a wrong address or the patient was deceased. Furthermore, 145 (12%) participants who completed the questionnaires were excluded because they did not meet the study criteria (n=57) or because of missing data (n=88). Thus, the final sample was composed of 600 participants (35% of the solicited patients or 52% of the patients who returned their mailing package with the consent form), including 228 (38%) with breast cancer, 246 (41%) with prostate cancer, 78 (13%) with colorectal cancer, and 48 (8%) with lung cancer. Demographic and medical characteristics for each cancer subgroup are presented in Table 1.

Measures

Concerns About Recurrence Scale (CARS) This questionnaire [41] is divided into two main sections. In the first section, overall FCR is assessed by means of four questions (i.e., frequency, potential for upset, consistency, and intensity of fears) using a six-point Likert scale, for a total score ranging from 4 to 24. In the second section, the nature of women's fear about breast cancer recurrence is assessed using 26 items on a Likert scale ranging from 1 (a little) to 4 (extremely). A higher score indicates increased levels of worry about potential consequences of cancer recurrence. The original English version was found to have adequate internal consistency (α=0.93) [41]. A French-Canadian

Table 1 Participants' characteristics by cancer site

	Breast (n=227)	Prostate (n=246)	Colorectal (n=78)	Lung (n=49)
Mean age (SD)	59.0 (0.6)	69.1 (0.5)	61.6 (1.3)	62.0 (1.5)
Gender (%)				
Female	100	0	44.9	38.8
Male	0	100	55.1	61.2
Marital status (%)				
Single	32.5	22.8	32.1	38.8
Married /with partner	67.5	77.2	67.9	61.2
Education				
Primary diploma or less	5.3	9.9	6.6	10.6
High school diploma	5.7	12.4	10.5	14.9
College degree	45.6	37.8	35.5	40.4
University degree	43.4	39.9	47.4	34.0
Employment (%)				
Retired	44.5	76.4	50.0	59.2
Working (full/part time)	37.4	21.9	29.5	16.3
Other (sick leave or homemaker)	18.1	1.7	20.5	24.5
Time since diagnosis (mean years/SD)	4.9 (0.2)	4.9 (0.2)	4.2 (0.2)	3.8 (0.5)
Cancer treatments received (%)				
Surgery	69.2	45.9	67.9	44.9
Radiotherapy	95.2	62.2	66.7	67.3
Chemotherapy	47.6	3.2	74.4	36.7
Cancer recurrence (%)				
Localized	15.0	17.5	20.5	28.6
Metastatic	11.0	11.0	23.1	28.6

version of the CARS was developed for the purpose of this study and adapted by our research team for patients with cancer sites other than breast cancer.

Fear of Recurrence Questionnaire (FRQ) This 22-item scale assesses the amount of concern that patients entertain about the probability of the illness returning in the future using a five-point bipolar scale (i.e., strongly agree to strongly disagree) [32]. A higher score indicates a higher FCR level (range from 22 to 110). Adequate reliability (α=0.92) and content validity of the original English scale have been reported [18]. The French-Canadian version was developed by our research team for the purpose of this study.

Illness Worry Scale (IWS) This nine-item questionnaire evaluates the tendency to interpret bodily sensations or feelings as an indication of the presence of a serious disease and the perceived vulnerability to becoming ill [35]. The French-Canadian version possesses adequate psychometric qualities [22]. The items are evaluated on a Likert scale ranging from 0 (not at all) to 4 (extremely), with a global score raging from 0 to 36.

Hospital Anxiety and Depression Scale (HADS) This questionnaire includes 14 items divided into two subscales: depression (HADS-D, seven items) and anxiety (HADS-A, seven items) [45]. The HADS does not contain any somatic items that could be confounded with symptoms associated with a physical illness. Scores obtained for each subscale range from 0 to 21. The French-Canadian version proved to possess psychometric qualities equivalent to the original English version [36].

Impact of Event Scale (IES) This questionnaire includes 15 items divided in two subscales: intrusion (seven items, scores range from 0–35) and avoidance (eight items, scores range from 0–40) [19]. The IES provides a measure of symptoms relating to a specific traumatic experience. The French-Canadian version possesses adequate psychometric qualities [6]. In this study, the traumatic event identified in the instructions was the cancer diagnosis.

European Organization for Research and Treatment (EORTC) of Cancer Quality of Life Questionnaires (QLQ-C30 + 3) This questionnaire was developed and validated to assess the quality of life of cancer patients [1]. Only five subscales were used in this study, comprising a total of 16 items that assessed the global quality of life, as well as physical (e.g., the ability to take a short walk), cognitive (e.g., ability to concentrate), social (e.g., family life), and role (e.g., work and recreation) functioning. Scores are transformed from 0 to 100, and a higher score indicates a better functioning. The French version was developed by the authors of the original English version.

Procedure

Randomly selected patients received a mailing package containing a letter explaining the goals of the study, a consent form, and the battery of self-report questionnaires. The patients who agreed to participate were asked to complete the battery of questionnaires within 2 weeks and return them by mail. Those who failed to return the mailing package within 6 weeks were sent a reminder by mail. Participants were asked for their consent to be solicited to complete the same battery of questionnaires a second time at an average interval about 1 month after the initial completion. Among the 300 patients who received the second battery of questionnaires, 288 (96%) returned the questionnaires completed. This study was approved by the research and ethics committee of the CHUQ-L'HDQ.

Quotation and English translation

Each item of the FCRI is rated on a Likert scale ranging from 0 (not at all or never) to 4 (a great deal or all the time). A total score can be obtained for each subscale and for the total scale by summing the items. The quotation of item 9 ("I believe that I am cured and that the cancer will not come back") must be reversed before the summation. A higher score indicates higher levels of FCR.

The FCRI that was initially developed in French was translated into English to make it more universally available for cancer research and care. A forward–backward translation was used [26]. Specifically, the final version of the FCRI, composed of 42 items, was first translated from French into English by two independent translators whose mother tongue was English. These two translations were reviewed and compared with the French-Canadian version by two independent bilingual researchers in clinical psycho-oncology whose mother tongue was also English. They were asked to compare the French-Canadian and the English versions to select the best translations provided for each item and to suggest another formulation if none of the translations were judged satisfactory. The objective was to focus on conceptual and cross-cultural equivalence rather than linguistic/literal equivalence. The problematic items (n=8) were again submitted to the translators and to the experts until a consensus was obtained (two iterations).

Statistical analysis

The data were examined and verified using standard procedures [40]. Analyses were conducted using SPSS 11.01 software [37]. The alpha level was set at 5%. An exploratory factor analysis with an oblique (Promax) rotation was conducted to identify the factorial structure of the French-Canadian version of the FCRI. The oblique rotation was chosen because strong correlations were expected between factors. Descriptive statistics were computed to characterize the sample. One-way ANOVAs were conducted to compare FCR across cancer sites. To estimate the reliability of the FCRI, the coefficient alpha [9] was calculated in addition to item-total correlations. Also, for the assessment of test–retest reliability, correlations were computed between FCRI scores obtained on two different occasions, separated by an interval of 1 month. Four strategies were undertaken to evaluate the validity of the FCRI. Firstly, construct validity was evaluated by assessing the FCRI convergence with other FCR measures (i.e., CARS, FRQ) and a measure of fear of illness (i.e., IWS). Secondly, concurrent validity was examined by calculating correlations between FCRI scores with anxiety and depression scores (i.e., HADS) and with intrusion and avoidance scores (i.e., IES). Although FCR is a somewhat distinct construct from psychological distress or PTSD symptoms, it is commonly associated with them, thus justifying using it as a criterion. Thirdly, divergent validity was evaluated by assessing the FCRI divergence with a quality of life measure (i.e., QLQ-C30 + 3). Finally, discriminant validity was assessed by computing correlations between FCRI scores and some demographic and medical characteristics of cancer patients.

Results

Item reduction

Descriptive statistics were computed for each item of the initial version of the FCRI (i.e., 75 items) to identify various possible problems: too high a proportion of missing data (≥10%), abnormal distribution (M≤0.5 or M≥3.5), absence of variance (SD≤0.5), poor item-total correlation (r≤0.20), and correlations between two items too elevated (r=≥0.75) [40]. Because they met more than one of these criteria, 20 items were eliminated from the subsequent analyses, thus leaving 55 items.

Factor analysis

The principal factor analysis was performed on these 55 items to identify meaningful subsets of items and to continue reducing the number of items. A factor analysis was conducted on each cancer site separately and on the total sample. The analyses below are those conducted on the total sample, as the factorial structure was consistent across cancer sites and because more than 550 observations were needed to perform an adequate factor analysis, given that the questionnaire comprised 55 items at that point [40]. The high value of the Kaiser factorability index (0.96) obtained indicated that the correlation matrix was suitable for

factor analysis. The criterion used for assigning an item to a factor was a factor loading ≥0.35. Item loadings that were lower than 0.35 (n=13) on more than one factor were eliminated from the questionnaire [40], thus leaving 42 items in the final version of the FCRI. Solutions with between five to eight factors were explored. The criteria used for selecting the best structure were the magnitude of the percentage of variance obtained and the degree of coherence with our cognitive-behavioral conceptualization of FCR.

A total solution with seven factors was selected (see Table 2), which accounted for 64% of the variance. The first factor, triggers, comprises eight items of which seven assess specific situations that make one think about the possibility of a cancer recurrence and one item that assesses to how far these situations are generally avoided. The second factor, severity, includes nine items that assess the presence, the frequency, the intensity, and the duration of the thoughts associated with FCR, the perceived risk of recurrence, the legitimacy of worrying about cancer recurrence, and the presence of other unpleasant thoughts or images that come to mind in association with FCR. Moreover, it comprises one reverse item assessing the belief that one is cured. This item makes it possible to control for automatic patterns of response. The third factor, psychological distress, includes four types of emotions frequently triggered by thoughts about cancer recurrence. The fourth factor, coping strategies, comprises nine strategies that may be used to cope with FCR. The fifth factor, functioning impairments, includes six domains of functioning that can be disturbed by FCR. The sixth factor, insight, contains three items assessing the extent to which the patients perceive their fear as excessive or unreasonable. The seventh factor, reassurance, comprises three reassurance behaviors specific to FCR. Intercorrelations obtained between all FCRI factors are presented in Table 3. Strong correlations were obtained varying from 0.27 to 0.85 (all p_s=0.001), which suggests that a total FCRI score could be used to assess global manifestations of FCR [40]. The strong correlations obtained between the severity factor and the total FCRI score, $r(599)=0.84$, $p<0.001$, suggest that the severity subscale could be used to provide a brief FCR assessment including screening.

Reliability

An overall Cronbach's alpha of 0.95 and item-total correlations ranging from 0.26 to 0.82 (all $p_s<0.001$) were obtained (see Table 3). In fact, all items but one had a correlation greater than 0.35 with the total score. This item ("I believe that I am cured and that the cancer will not come back") was nonetheless maintained in the FCRI because it is the only reversed item and because it is strongly associated with the severity factor, $r(599)=0.39$, $p<0.001$.

Table 2 Factor structure of the Fear of Cancer Recurrence Inventory (FCRI)

	Factor pattern loading
Factor 1—triggers	
Conversations about cancer or illness in general	0.87
Seeing or hearing someone who's ill	0.86
Television shows or newspaper articles about cancer or illness	0.82
Going to a funeral or reading the obituary section of the paper	0.80
An appointment with my physician or other health professional	0.77
Physical examination (annual check-up, blood tests, X-rays)	0.76
When I feel less well physically or when I am sick	0.59
Generally, I avoid situations or things that make me think about the possibility of cancer recurrence (PCR)	0.42
Eigenvalue=5.1	Explained variance=12.2%
Factor 2—severity	
How long have you been thinking about the PCR?	0.84
How many times per day do you spend thinking about the PCR?	0.81
How often do you think about the PCR?	0.80
In your opinion, what is your risk of having a cancer recurrence	0.68
I am afraid of a cancer recurrence	0.63
I am worried or anxious about the PCR	0.60
I believe that I am cured and the cancer will not come back	0.57
I think it's normal to be anxious or worried about the PCR	0.51
When I think about PCR, other unpleasant thoughts or images come to mind (death, suffering, consequences for my family)	0.45
Eigenvalue=4.9	Explained variance=11.7%
Factor 3—psychological distress	
Frustration, anger or outrage	0.79
Sadness, discouragement or disappointment	0.62
Helplessness or resignation	0.57
Worry, fear or anxiety	0.43
Eigenvalue=4.6	Explained variance=10.9%
Factor 4—coping strategies	
I try to replace this thought with a more pleasant one	0.87
I try to convince myself that everything will be fine or I think positively	0.83
I try to get the idea out of my mind, to not think about it	0.80
I try to distract myself (e.g. do various activities, watch TV, read, work)	0.77

Table 2 (continued)

	Factor pattern loading
I try to understand what is happening and to deal with it	0.60
I tell my self "stop it"	0.59
I pray, meditate or do relaxation	0.59
I try to find a solution	0.58
I talk to someone about it	0.48
Eigenvalue=3.6	Explained variance=8.7%
Factor 5—functioning impairments	
My social or leisure activities (e.g. outings, sports, travel)	0.83
My quality of life in general	0.77
My ability to make future plans or set life goals	0.76
My work or everyday activities	0.75
My relationship with my partner, my family, or those close to me	0.72
My state of mind or my mood	0.66
Eigenvalue=3.5	Explained variance=8.4%
Factor 6—insight	
I feel that I worry excessively about the PCR	0.81
I think that I worry more about the PCR than other people who have diagnoses of cancer	0.69
Other people think that I worry excessively about the PCR	0.68
Eigenvalue=2.9	Explained variance=6.9%
Factor 7—reassurance	
I go to the hospital or clinic for an examination	0.81
I call my doctor or another health professional	0.81
I examine myself to see if I have any physical signs of cancer	0.44
Eigenvalue=2.0	Explained variance=4.7%

PCR possibility of cancer recurrence, *FCR* fear of cancer recurrence

Finally, a strong correlation was obtained between two administrations separated by a 1-month interval, $r(287)=0.89$, $p<0.001$ (see Table 3), thus supporting the test–retest reliability of the FCRI.

Descriptive statistics

Table 4 shows the means and standard deviations obtained on the FCRI for each cancer site. The FCRI total score for the whole sample was 51.7 (SD=28.8). Women obtained a significantly higher FCRI total score ($M=60.5$, SD=25.6) than men ($M=44.1$, SD=29.4), $t(598)=-7.25$, $p<0.001$. Significant differences were also found between cancer sites on all FCRI subscales and on its total score, with the exception of the insight subscale. Overall, prostate cancer patients reported lower levels of FCR than patients with other cancer sites. Moreover, lung cancer patients obtained higher scores on the functioning impairment subscale than patients with other cancer sites, but these differences were significant with breast and prostate cancer patients only.

To verify the influence of gender while controlling for the effect of cancer type, other analyses were conducted on the two types of cancer that affect both genders: lung and colorectal cancer. No significant differences were observed between men and women for these two subgroups [lung, $t(47)=0.463$, $p=0.65$; colorectal, $t(76)=-0.677$, $p=0.50$]. It thus appears that the type of cancer has more influence on FCR severity than gender.

Construct validity

Convergent validity Table 5 presents the correlations obtained between the FCRI factors and the total score and scales evaluating similar constructs, namely the CARS, the FRQ, and the IWS. As expected, strong correlations were found between the FCRI total score and the CARS overall fear subscale score, $r(599)=0.77$, $p<0.001$; the CARS nature of the fear subscale score, $r(599)=0.74$, $p<0.001$; the FRQ total score, $r(599)=0.71$, $p<0.001$; and the IWS total score, $r(599)=0.68$, $p<0.001$.

Concurrent criterion validity As expected, higher levels of FCR, assessed using the FCRI total score, were significantly associated with increased intrusive thoughts, $r(599)=0.66$, $p<0.001$; avoidance, $r(599)=0.52$, $p<0.001$; anxiety symptoms, $r(599)=0.64$, $p<0.001$; and depression symptoms, $r(599)=0.43$, $p<0.001$ (see Table 5). These results indicate that FCR is associated with psychological distress and cancer-related symptoms while remaining a distinct construct.

Divergent validity Table 6 presents the correlations obtained between the FCRI factors and total score, and some subscales of the QLQ-C30 + 3. Overall, low to moderate correlations were found between the FCRI total score and constructs assessed by the QLQ-C30 + 3 that are not believed to be directly associated with FCR, such as physical functioning, $r(599)=-0.22$, $p<0.001$, role functioning, $r(599)=-0.31$, $p<0.001$; cognitive functioning, $r(599)=-0.20$, $p<0.001$; social functioning, $r(599)=-0.35$, $p<0.001$; and global quality of life, $(599)=-0.36$, $p<0.001$. These correlations were all statistically significant, possibly because of the large sample size, but they were consistently of a smaller magnitude than those obtained with other measures of FCR or related constructs.

Table 3 Inter-correlations between Fear of Cancer Recurrence Inventory (FCRI) factors and reliability indices

FCRI factors	F1	F2	F3	F4	F5	F6	F7	Total	Item-total correlations	Cronbach's alpha	Test–retest (1 month)
F1—triggers	1.0	0.69*	0.71*	0.51*	0.49*	0.46*	0.36*	0.85*	0.42 to 0.79	0.90	0.83
F2—severity		1.0	0.69*	0.43*	0.52*	0.52*	0.35*	0.84*	0.26 to 0.78	0.89	0.80
F3—psychological distress			1.0	0.49*	0.60*	0.49*	0.44*	0.84*	0.64 to 0.79	0.86	0.76
F4—coping strategies				1.0	0.29*	0.26*	0.45*	0.74*	0.56 to 0.74	0.89	0.75
F5—functioning impairments					1.0	0.50*	0.36*	0.68*	0.69 to 0.82	0.91	0.70
F6—insight						1.0	0.27*	0.59*	0.64 to 0.68	0.80	0.58
F7—reassurance							1.0	0.56*	0.49 to 0.65	0.75	0.73
Total score								1.0	0.26 to 0.82	0.95	0.89

*$p<0.001$

Discriminant validity A higher FCRI total score was significantly associated with younger age, $r(599)=-0.31$, $p<0.001$; and with female gender, $r_s(599)=0.31$, $p<0.001$. However, there was no significant association with education level, $r_s(599)=0.06$, $p=0.21$. Additionally, a significantly higher FCRI total score was found in patients who had received chemotherapy, $r_s(599)=0.26$, $p<0.001$; radiotherapy, $r_s(599)=0.12$, $p=0.005$; and surgery, $r_s(599)=0.10$, $p=0.011$; and patients who had had a localized, $r_s(599)=0.12$, $p=0.003$; or metastatic cancer progression, $r_s(599)=0.14$, $p=0.001$. On the other hand, no significant association was found with the time elapsed since the cancer diagnosis, $r(599)=-0.001$, $p=0.99$. Additional analyses were conducted on men and women separately, as well as on the different cancer types. Except for the absence of a significant association obtained between the severity of FCR and chemotherapy in prostate cancer patients (but only 3% of patients had received this type of treatment), the results (nature and strengths of association) were very comparable to those reported on the total sample.

Discussion

Although FCR has often been identified among the most frequent psychological disturbances in cancer patients, few studies have been carried out specifically on this complex issue. This may be at least partly explained by the lack of a validated instrument to assess the multidimensional aspects of FCR. The goal of this study was to develop and provide preliminary validity data for the FCRI in patients with various cancer sites. The development of this new self-report scale was guided by a cognitive–behavioral conceptualization of FCR [25], and because of the anxious nature of FCR, efforts were made to include items reflecting the DSM-IV diagnostic criteria [2] for anxiety disorders (e.g., triggers, reassurance, insight, coping strategies, and functional impairments). The final French-Canadian version of the FCRI, which was obtained following a standardized multi-step methodology, contains 42 items coherent with the cognitive–behavioral conceptualization that underlined the development of the questionnaire. Overall, this study

Table 4 ANOVAs and multiple comparisons of the Fear of Cancer Recurrence Inventory (FCRI) by cancer site

FCRI factors	Number of items	Score range	Breast (n=227)		Prostate (n=246)		Colorectal (n=78)		Lung (n=49)		F (3,596)
			M	SD	M	SD	M	SD	M	SD	
Triggers	8	0–32	13.6_a	6.9	9.4_b	6.8	12.7_a	7.9	12.5_a	7.5	14.39*
Severity	9	0–36	14.3_a	7.6	10.7_b	7.3	13.8_a	8.4	14.6_a	7.7	10.42*
Psychological distress	4	0–16	5.4_a	3.8	3.3_b	3.5	6.0_a	4.8	5.3_a	4.2	16.85*
Coping strategies	9	0–36	19.3_a	7.5	11.2_b	8.5	17.6_a	8.7	17.3_a	8.9	41.53*
Functioning impairments	6	0–24	$3.1_{b,c}$	4.1	2.7_c	4.3	$4.5_{a,b}$	5.6	5.1_a	6.5	5.92*
Insight	3	0–12	1.7	2.4	1.5	2.3	2.0	2.8	2.1	2.8	1.29 ns
Reassurance	3	0–12	3.2_a	2.9	1.0_c	1.8	2.3_b	2.9	2.0_b	2.6	31.06*
Total score	42	0–168	60.6_a	24.6	39.8_b	26.4	58.8_a	32.6	58.9_a	31.3	26.86*

Means with different subscripts are significantly different at α=0.05 according to the REGW multiple comparison test.
ns no significant, *$p<0.001$

Table 5 Correlations obtained between the Fear of Cancer Recurrence Inventory (FCRI) factors and other measures

Measures	*M*	SD	Alpha	FCRI factors							
				F1	F2	F3	F4	F5	F6	F7	Total
Convergent validity											
CARS-Overall fear	1.3	1.0	0.93	0.66*	0.77*	0.72*	0.44*	0.54*	0.50*	0.36*	0.78*
CARS-Nature of fear	2.3	1.2	0.97	0.64*	0.66*	0.69*	0.50*	0.48*	0.35*	0.37*	0.74*
FRQ	71.4	14.9	0.90	0.63*	0.71*	0.60*	0.42*	0.49*	0.40*	0.31*	0.71*
IWS	5.1	6.2	0.85	0.60*	0.59*	0.63*	0.33*	0.58*	0.56*	0.36*	0.68*
Concurrent criterion validity											
IES-Intrusion	8.6	8.0	0.88	0.62*	0.55*	0.62*	0.43*	0.49*	0.40*	0.32*	0.66*
IES-Avoidance	13.6	9.9	0.84	0.53*	0.35*	0.44*	0.46*	0.28*	0.31*	0.25*	0.52*
HADS-Anxiety	5.3	3.9	0.82	0.54*	0.57*	0.61*	0.36*	0.52*	0.43*	0.36*	0.64*
HADS-Depression	2.9	3.3	0.81	0.34*	0.38*	0.44*	0.11*	0.57*	0.33*	0.23*	0.43*

F1 triggers, *F2* severity, *F3* psychological distress, *F4* coping strategies, *F5* functioning impairment, *F6* insight, *F7* reassurance, *total* total score, *CARS* Concerns About Cancer Recurrence Scale, *FRQ* Fear of Recurrence Questionnaire, *IWS* Illness Worry Scale, *IES* Impact of Event Scale, *HADS* Hospital Anxiety and Depression Scale
*$p<0.001$

supported the reliability and validity of this multidimensional measure in cancer patients.

Results of the factorial analyses revealed a clear structure and indicated the presence of seven distinct factors: triggers, severity, psychological distress, coping strategies, functioning impairments, insight, and reassurance. The factors obtained reflect the principal characteristics of FCR [25, 41, 42] and anxiety disorders [2]. The triggers subscale evaluates the presence of potential stimuli activating FCR. The psychological distress and functioning impairments subscales evaluate the potential consequences of FCR. The insight subscale measures the level of self-criticism towards FCR intensity. The reassurance and coping strategies subscales measure a variety of coping strategies that can be used to cope with FCR severity [25, 42] including denial, wishful thinking, cognitive avoidance, or reassurance (the more patients present an elevated level of FCR, the more they use these different coping strategies). The FCRI severity subscale measures the presence and the severity of the intrusive thoughts or images associated with FCR, and it can be used separately as a short form of the FCRI for the brief screening of FCR and as an outcome measure. Alternatively, the strong correlations obtained between the seven subscales suggest that the FCRI total score can be used to measure FCR more globally. In sum, the diversity of the measure content of the FCRI is a good reflection of the complexity and the multidimensional nature of FCR. It also targets some diagnostic criteria essential to assess the continuum between normal to clinically significant FCR.

The internal stability obtained for the FCRI total score and for each subscale was excellent, as well as the test–retest reliability at a 1-month interval, thus supporting the scale reliability. The validity of the FCRI was also supported by the study results. Firstly, the convergent validity of the FCRI with other measures of FCR and related constructs was supported. The correlations observed between the FCRI and the corresponding constructs were all significant and moderate to strong in magnitude.

Table 6 Correlations obtained between the Fear of Cancer Recurrence Inventory (FCRI) factors and other measures

Measures	*M*	SD	Alpha	FCRI factors							
				F1	F2	F3	F4	F5	F6	F7	Total
Divergent validity (QLQ-C30 + 3)											
Physical functioning	86.5	20.6	0.65	−0.14*	−0.19*	−0.17*	−0.07	−0.31*	−0.21*	−0.15*	−0.22*
Role functioning	84.3	24.5	0.80	−0.22*	−0.27*	−0.28*	−0.13**	−0.40*	−0.20*	−0.17*	−0.31*
Cognitive functioning	83.4	21.3	0.67	−0.15*	−0.17*	−0.20*	−0.09**	−0.22*	−0.14*	−0.18*	−0.20*
Social functioning	85.7	23.0	0.84	−0.26*	−0.29*	−0.33*	−0.14*	−0.41*	−0.30*	−0.23*	−0.35*
Global quality of life	75.0	19.7	0.92	−0.27*	−0.38*	−0.33*	−0.10**	−0.42*	−0.29*	−0.19*	−0.36*

F1 triggers, *F2* severity, *F3* psychological distress, *F4* coping strategies, *F5* functioning impairment, *F6* insight, *F7* reassurance, *total* total score, *QLQ-C30 + 3* EORTC Quality of Life Questionnaire
*$p<0.001$, **$p<0.05$

Secondly, the concurrent criterion validity of the FCRI was supported. This type of construct validity aims to assess whether the measure performs in accordance with theoretical expectations [3]. For the FCRI, we expected, based on the existing literature [25], that FCR would be significantly associated with psychological distress and more specifically with anxiety [20]. Strong correlations with intrusions and avoidance behavior were also expected because of the potentially traumatic nature of cancer recurrence [7]. As expected, weak to strong correlations were observed between the FCRI total and subscales scores and anxiety symptoms, intrusive thoughts, and avoidance scores, while slightly weaker correlations with depression were found. Nevertheless, the correlations observed, which were of a lower magnitude than those obtained with other FCR measures and varying across subscales, revealed that the FCRI assesses a construct close to but nevertheless distinct from general psychological distress or cancer-specific anxiety.

Thirdly, the divergent validity of the FCRI was also supported by obtaining low to moderate correlations between FCRI scores and specific subscales of a quality of life questionnaire (QLQ-C30 + 3). Thus, although FCR can have a deleterious impact on quality of life indices (i.e., physical, role, cognitive, social) or global quality of life [25, 42], FCR was established as a construct distinct from its potential consequences. Finally, the FCRI showed that it could discriminate accurately among patients according to their age, gender, cancer progression, and the fact of having received more aggressive cancer treatments (i.e., chemotherapy). However, education level and the time elapsed since cancer diagnoses were not found to be associated with the FCR severity. The latter result, which is consistent with some others studies [25, 28], suggests that FCR is somewhat stable over time.

There are some limitations to our study. All participants in this study were French-Canadian patients and Caucasian. Thus, transcultural studies would be useful to evaluate the validity of the FCRI in other cultures and in different languages, including English. Indeed, although the FCRI was rigorously translated into English in this study, this version was not empirically validated. Also, because psychometric properties were assessed mainly using only one sample of a heterogeneous group of cancer patients, other studies are necessary to confirm the structure and the psychometric properties of the FCRI across cancer sites and cancer stages. Moreover, further clinical studies are necessary to evaluate the FCRI's sensitivity to change. In addition, because recruitment was done by mail and the participation rate was only of 35% of the solicited patients (or 52% of the patients who returned their study package), it is possible that our sample is not representative of the cancer population. For instance, some individuals with more severe levels of FCR may not have participated in our study because of their tendency to use avoidance as a coping strategy. Finally, additional research is needed on the definition and detection of clinical levels of FCR requiring clinical attention. Along these lines, a separate manuscript will report findings on the capacity of the severity subscale of the FCRI to detect clinical levels of FCR (Simard et al., in preparation).

The FCRI is the first empirically validated questionnaire that has been made available to evaluate the multidimensional aspects of FCR. The FCRI could become extremely useful to gain a better understanding of FCR and to serve as on outcome measure in future clinical research.

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