Accepted refereed manuscript of: Bergerot CD, Ferreira LN, Molina LNM, Pagung LB, Pedersen BdS, de Andrade TG, Machado RHI, Freitas ANdS, Barreto LHCT, de Araujo LL, Tumeh IBRG, Vieira NBS, Lee D, Philip EJ, Neto JNM, Buso MM, Simard S, Ozakinci G, Humphris G, Bergerot PG & Smith AB (2023) Fear of cancer recurrence among Brazilian patients with cancer: Translation and cultural adaptation of FCR4/7 and FCRI-SF measures. *Journal of Psychosomatic Research*, 165. https://doi.org/10.1016/j.jpsychores.2022.111125

FULL LENGTH PAPERS

Fear of Cancer Recurrence among Brazilian patients with cancer: Translation and cultural adaptation of FCR4/7 and FCRI-SF measures

Cristiane Decat Bergerot, PhD[1]; Leticia Norata Ferreira[1]; Lorena Nascimento Manrique Molina[1]; Larissa Bessert Pagung[2]; Bianca da Silva Pedersen[3]; Thais Gonçalves de Andrade[1]; Raquel Helena Iinuma Machado[4]; Alici Natalia de Sousa Freitas[1]; Lucia Helena Cavalcanti Toscano Barreto[5]; Luciana Lima de Araujo[5]; Isabella Barros Rabelo Gontijo Tumeh, PhD[6]; Natalia Barros Salgado Vieira[1]; David Lee[7]; Errol J. Philip, PhD[8]; João Nunes Matos Neto, MD, PhD[1]; Marco Murilo Buso, MD[1]; Sebastien Simard, PhD[9]; Gozde Ozakinci, PhD[10]; Gerald Humphris, PhD[11]; Paulo Gustavo Bergerot, MD[1*]; Allan 'Ben' Smith, PhD[12*]

* Both authors contributed equally to this work

1. Centro de Câncer de Brasília, Instituto Unity de Ensino e Pesquisa, Brasília, DF, Brazil
2. Medquimheo – Oncologia e Hematologia, Vitoria, ES, Brazil
3. Instituto de Oncologia Kaplan, Porto Alegre, RS, Brazil
4. Sensumed Oncologia, Instituto de Cancer de Manaus, Manaus, AM, Brazil
5. Centro Pernambucano de Oncologia, Recife, PE, Brazil
6. Hospital Araujo Jorge, Goiania, GO, Brazil
7. University of New Mexico, Albuquerque, NM, USA
8. University of California San Francisco, San Francisco, CA, USA
9. Health Science Department, Université du Québec à Chicoutimi (UQAC), Saguenay, QC, Canada
10. Division of Psychology, Faculty of Natural Sciences, University of Stirling, United Kingdom
11. Population and Behavioural Sciences, School of Medicine, University of St. Andrews, Scotland, UK.
12. Faculty of Medicine and Health, South West Sydney Clinical Campuses, University of New South Wales (UNSW Sydney), Liverpool, Australia

Keywords: Cancer; Fear of cancer recurrence; Fear of cancer recurrence inventory-short form; Fear of cancer recurrence-7; confirmatory factor analysis; Psychometrics

Running head: Portuguese version of the FCRI-SF and FCR4/7

Corresponding Author:
Paulo Gustavo Bergerot, MD
Centro de Câncer de Brasília, Instituto Unity de Ensino e Pesquisa
SMH/N Quadra 02, Ed de Clínicas, 12º andar
E-mail: paulobergerot@gmail.com
Phone: +55(61)3429-2900

Allan 'Ben' Smith, PhD
Faculty of Medicine and Health, South West Sydney Clinical Campuses, University of New South Wales (UNSW Sydney), Liverpool, Australia
E-mail: ben.smith@unsw.edu.au

Total text page: 2870
Total words (abstract): 4810 (250)
Tables/Figures: 4/0

Financial Disclosure: Nothing to disclosure.
Funding: This study was not funded.
Declaration of Interest Statement: None
Data availability statement: The data that support the findings of the paper are available from the corresponding author upon reasonable request.

Accepted refereed manuscript of: Bergerot CD, Ferreira LN, Molina LNM, Pagung LB, Pedersen BdS, de Andrade TG, Machado RHI, Freitas ANdS, Barreto LHCT, de Araujo LL, Tumeh IBRG, Vieira NBS, Lee D, Philip EJ, Neto JNM, Buso MM, Simard S, Ozakinci G, Humphris G, Bergerot PG & Smith AB (2023) Fear of cancer recurrence among Brazilian patients with cancer: Translation and cultural adaptation of FCR4/7 and FCRI-SF measures. *Journal of Psychosomatic Research*, 165. https://doi.org/10.1016/j.jpsychores.2022.111125

ABSTRACT

Objective: Fear of cancer recurrence or progression (FCR) is considered one of the most common unmet needs among patients with cancer. This study sought to translate and evaluate the psychometric properties of the Fear of Cancer Recurrence scale (FCR4/7) and Fear of Cancer Recurrence Inventory-Short Form (FCRI-SF).

Methods: This study involved three phases: (1) translation and cultural adaptation of the FCR4/7 and FCRI-SF measures, (2) validity and reliability testing of the Portuguese version of these measures, and (3) examining patient's perceptions of these measures. Eligible patients were diagnosed with localized breast cancer, and patients with metastatic cancer. Descriptive analyses were collated, and psychometric analysis were conducted (confirmatory factor analysis).

Results: A total of 200 patients were recruited (100 patients with localized and 100 patients with metastatic cancer). A significant proportion of patients reported moderate to severe FCR (FCR7: 32.0% and FCRI-SF: 43.0%). Female gender, younger age and metastatic cancer were associated with higher levels of FCR. Psychometric analyses suggested that the Portuguese versions of the FCR4/7 and FCRI-SF were valid, unidimensional in nature, with acceptable reliability coefficients across all scales. In a sub-sample qualitative analysis (n=75), most patients were satisfied with the relevance of both measures.

Conclusion: Our findings suggest the Portuguese versions of the FCR4/7 and FCRI-SF are valid tools to assess FCR among patients with localized and metastatic cancer. Future research can now extend our understanding of FCR and assess this construct among Portuguese speaking patients, to guide the development of effective and targeted interventions for patients globally.

INTRODUCTION

Fear of cancer recurrence or progression (FCR) is considered one of the most common unmet needs reported by patients with cancer [1,2]. Defined as the "fear, worry or concern relating to the possibility that cancer will come back or progress", clinical FCR is characterized by "high levels of preoccupation, high levels of worry, persistence, and hypervigilance to bodily symptoms" [3,4]. Importantly, despite the fact that fear of cancer recurrence and fear of cancer progression have been treated as synonymous constructs, a recent study has suggested that these may be distinct entities, particularly in the context of advanced disease, whereby terminology such as remission and recurrence are less utilized [5]. Importantly, the impact of FCR on patients' lives may differ based on their stage of disease, and thus research efforts are needed to develop validated tools among those with both localized and advanced disease [5].

A recent meta-analysis (46 studies comprising 11,226 participants from 13 countries) revealed a high prevalence of FCR, with 59% of patients reporting moderate (40%) to severe (19%) symptoms [6]. The sample was composed of patients with localized and metastatic cancer, primarily diagnosed with breast, prostate, and colorectal cancers. Notably, however, most of the data included in this meta-analysis came from English-speaking patients in high-income countries (HIC) [6]. To date, few studies have examined the experience of patients in Brazil or other Latin American countries, or among countries classified as low- and middle- income (LMICs) generally [6,7]. To accurately evaluate FCR and guide service provision in non-English speaking patients from LMICs, it is essential that FCR measures be translated and validated.

Numerous validated measures have been developed to assess FCR [8]. One of the most widely used and validated measures in this domain is the 9-item Fear of Cancer Recurrence Inventory-Short Form (FCRI-SF) [9,10]. The more recently developed 4- and 7-item Fear of Cancer Recurrence scale (FCR4/7) assesses characteristics of clinical FCR and may be more

suited to clinical use given its brevity [11]. However, it is important to note that FCR7 has only 2 items less than the FCRI-SF. These tools play an important role in identifying patients with clinically relevant FCR and guide supportive care, particularly given that more severe FCR has not been shown to improve over time without evidence-based psychosocial intervention [12, 13]. Both measures assess a variety of key features of FCR. The FCRI-SF includes severity of a symptom, coping, functioning impairments, triggers, insight, duration, and reassurance [9, 13]. In contrast, the FCR4 assesses symptoms of anxiety and worry concerning recurrence, while the FCR7 extends upon these items to include a cognitive processing component and behavioral responses [11].

Research is required to translate and culturally validate FCR measures to help clinicians and researchers better address this need among patients from LMICs across the cancer care continuum. In Brazil, for example, there are no data regarding the prevalence of FCR, nor any validated FCR measures translated into Portuguese. Given the relevance of the FCRI-SF and the FCR4/7 for clinical and research purposes [8], the current study sought to translate and evaluate the psychometric properties of these measures in two populations from Brazil: patients with localized breast cancer and patients with metastatic heterogeneous cancer. In addition, we sought to determine patients' perspectives regarding the relevance of these measures in a random sample of patients from these cohorts.

METHODS

This prospective study, approved by the Santa Marta ethics committee (Protocol #59399922.1.0000.8101), involved three phases: (1) translation and cultural adaptation of the FCR4/7 and FCRI-SF measures, (2) validity and reliability testing of the Portuguese version of

these measures, (3) examination of patients' perspectives regarding the relevance of these measures.

Participants

Patients were recruited from cancer centers located in 5 different states in Brazil encompassing the north, northeast, central west, southwest, and south of the country. Eligible patients were diagnosed with localized breast cancer (completed cytotoxic treatment at least one year prior to enrolment) or metastatic cancer of any kind, receiving treatment at a private practice from the group Unity, and willing to participate in this study. Consecutive patients were identified, recruited, and screened by the supportive care team.

Phase 1: Transcultural translation

Authors of the original FCR4/7 and FCRI-SF gave permission to translate, culturally adapt and validate the Portuguese version of both measures. The Beaton and colleagues' guidelines were used, including translation, synthesis, back-translation, expert committee review, and pretesting [14]. Two qualified translators Brazilian Portuguese native speakers were invited to participate and translate both measures independently. The translated versions were compared (Version 1.0 of FCR4/7 and Version 2 of FCRI-SF) and discrepancies were discussed and adjudicated by consensus. Notably, few discrepancies were identified, and they were not related to the content, but the wording. For example, the term "get waves of strong feelings" and "unpleasant thoughts or images". Thus, the resulting versions of both measures were back translated from Portuguese to English and reviewed by a qualified translator native English speaker. In addition, validation was undertaken with the developer of each scale. These preliminary versions in Portuguese were discussed with a group of experts (psychologists,

nutritionists, nurses, and medical oncologists) and an expert in semantics and idiomatic/cultural differences and consensus reached on any discrepancies. These versions were pilot tested with 10 patients to ensure valid interpretation and understanding of the measures. We conducted an interview to check if patients understood both measures. All pilot participants confirmed clarity of comprehension for both scales.

Phase 2: Construct validity of FCR Measures

Aligned with the characteristics of the population seen at these cancer centers, our sample was composed of two groups:

1. Localized breast cancer (n=100): A consecutive sample of patients who had completed their cytotoxic treatment at least one year prior to enrolment in this study, were invited to participate in the second phase of this study.
2. Metastatic cancer (n=100): a consecutive sample of patients with any type of metastatic cancer and receiving treatment at these cancer centers were also invited.

Patients who agreed to participate signed a consent form and completed both the FCR4/7 and FCRI-SF measures (details below).

Phase 3: Patients' perceptions of these measures

A consecutive sub-sample of study patients (N=75; 40 patients from the localized breast cancer group and 35 patients form the metastatic cancer group) were invited to participate in a brief interview comprising two open-ended questions exploring their views of these measures. They have answered to these questions after answering to the FCR7 and FCRI-SF:

- Please, we would like to ask you which of these measures (FCR7 and FCRI-SF) did the best job of capturing elements related to your FCR?

- Can you specify which items worked well or suggest changes that should be done to improve them?

Measures

- Sociodemographic: Four items related to gender, age, marital status, and level of education were collected. In addition, health-related information was recorded from the patients' medical record, including type of cancer, date of diagnosis, disease stage and treatment received.

- Fear of Cancer Recurrence (FCR 4/7): The FCR7 comprises 7 questions, 6 using a 5-point Likert scale, ranging from 1 'not at all' to 5 'all the time', and one using a 11-point Likert scale ranging from 0 'not at all' to 10 'a great deal' [15]. Total scores range from 6 to 45. A cutoff score of 17 or above is considered moderate FCR, and 27 or above, severe FCR. The FCR4 comprises the first four items of the FCR7. Based on the original paper, the reliability coefficients were above 0.9 for both scales [15]. A previous study noted that the internal consistency of FCR4 was .93 and FCR7 was .92 [15].

- Fear of Cancer Recurrence Inventory Short Form (FCRI-SF): composed of 9 questions that assess FCR. Six questions used a 5-point Likert scale (ranging from 0 'not at all or never or I don't think about it' to 4 'a great deal or several times a day or several hours or several years"), and three questions used a Likert scale with specific label (ranging from 0 'never or I don't think about it' to 4 'several') [16]. When calculating the score, item 5 is reversed coded. Scores range from 0 to 36. The recommended cutoff for clinical levels of FCR are 13 (moderate) and 22 (severe) [9,16]. Previous study has supported the internal consistency of .95 [16].

- Open-ended questions regarding the perception of these measures.

Statistical analysis

Descriptive analysis was used to characterize the sample. The proportion of patients with moderate to severe FCR was calculated considering the cut-offs established in the literature (see above) [9,14,16]. The Spearman correlation statistic was used to examine associations between clinical characteristics and FCR.

For the psychometric analysis of the FCR4/7 and FCRI-SF, we conducted a confirmatory factor analysis to determine how well the unidimensional structure of the Portuguese version of both measures fitted our proposed measurement model [17]. A single latent variable was constructed for each of the scales and respective indicators, that is the items featured in the published scales, were entered into the statistical model using *sem* procedure in STATA [18]. The output was inspected to assess goodness of fit using conventional criteria (CFI > .95; SRMR < .05; RMSEA < .1) [19, 20]. Standardized solutions were inspected for the presence of Heywood cases. The software adopted raising of alerts with computational processes. Ease of fit was also assessed secondarily by the level of iterations required under the maximum likelihood (ML) estimator. A limited number of iterations in order to converge was considered a helpful signal of reasonable fit. Modification indices were inspected to assess 'strain' in the measurement model. The inclusion of a limited number of correlated errors was introduced for each scale where necessary and when some theoretical explanation made such a measurement change acceptable. These analyses were rerun using a robust ML estimator which is insensitive to distributional violations of normality in the variables entered into the various models. We had considered conducting categorical CFA, however it has been concluded that with five or more categories of rating scales are appropriate for ML estimation [21]. In addition, we calculated the coefficient alpha with 95% confidence intervals for each scale to examine internal consistency. These *sem* analyses were run for the total sample size (N=200) and by subgroups (localized and metastatic). Results for the total sample will be presented unless differences were found by

subgroup comparisons. Analyses were conducted using the SPSS 27.0 and STATA15 software. Alpha (2-sided) of .05 was applied throughout.

Two independent reviewers (CB and PB) content analyzed open-ended question responses, organizing them into categories and calculating the prevalence of each response type. Patients' perspectives of these measures were characterized as centered around (1) both measures, (2) FCR4/7), (3) FCRI-SF, and (4) difficulties and suggestions. Discrepancies were discussed and adjudicated by consensus (Cohen's kappa coefficient = .89).

RESULTS

A total of 200 patients were enrolled: 100 with localized breast cancer and 100 with heterogeneous metastatic disease. Considering the total sample, patients had a median age of 58 years old, 79.0% were female, 68.5% were married, and 59.0% were college educated. Differences between patient groups are described in Table 1. Approximately one-third of participants reported moderate to severe FCR (FCR7: 32.0% and FCRI-SF: 43.0%). More patients with metastatic disease reported moderate to severe FCR (FCR7: 36.0% and FCRI-SF: 48.0%), compared with localized breast cancer patients (FCR7: 28.0% and FCRI-SF: 38.0%) (FCR7: p=.02; FCRI-SF: p=.001). Younger age correlated with higher levels of FCR (FCR7: r=-.86; p=.01 and FCRI-SF: r=-.75, p=.01). Female gender was significantly correlated with FCR (FCR7: r=.89, p=.003 and FCRI-SF: r=.71, p=.001) among metastatic cancer patients. No other demographic or clinical characteristics were associated with FCR, including marital status, education level, or time since diagnosis.

Psychometric analysis performed for both measures suggested that the Portuguese versions of the FCR4/7 and FCRI-SF are valid as unidimensional rating scales (Table 2). Item statistics (e.g., mean, standard deviation and skewness) are described in the Supplementary File.

Factor analysis demonstrated that all items had a high Cronbach's alpha (above .8 for the FCR4/7 and FCRI-SF, as shown in Table 3). In addition, the confirmatory factor analyses of all three scales demonstrated that the items comprising each assessment were loaded strongly on the respective latent variables. The large majority of the standardized factor loadings were high (i.e. above .5) and presented in Table 3. These results support the unidimensional finding. Further parallel factor analyses were conducted using Horn's procedure provided additional support (see Supplementary File). The exceptions to the strict measurement models tested were the two longer scales (FCR7 and the FCRI-SF). Each was found to have some relatively high modification indices (i.e., >10). To enable reasonable fit of raw data to the original measurement model two correlated errors were introduced into the FCR7 model and three correlated errors specified for the FCRI-SF. These are listed in Table 3 where fit indices are presented. The default maximum likelihood (ML) estimator results are presented. No substantive differences were found between these results and those listed using the robust ML option, hence the standard ML output is utilized. When each of these analyses were specified to assess equality of parameterization across the two disease severity groups (i.e., localized vs metastasized), none of the models converged. Hence, we were unable to examine group differences. The reliability coefficients were acceptable for all scales FCR4 (.879, 95%CIs: .855 to .904), FCR7 (.894, 95%CIs: .874 to .914) and FCRI-SF (.887, 95%CIs: .866 to .908) (Table 3). McDonald's omega coefficients are also presented in the Supplementary File.

In the third phase of this study, 75 consecutive patients (37.5% of the sample) answered two open-ended questions regarding these measures (Table 3). Interestingly, 41.3% of patients preferred the FCR4/7, especially due to the simplicity and brevity of the FCR4, while 17.3% preferred the FCRI-SF, as it was more comprehensive. Approximately one quarter (26.7%) of

patients liked both versions. Finally, 14.7% of patients reported issues with items and suggested changes for clarity. Items critiqued most frequently across both measures are listed in Table 4.

DISCUSSION

To our knowledge, this is the first time widely used measures of FCR have been translated and validated in Portuguese. Based on the psychometric analysis performed, the Portuguese version of the FCRI-SF and the FCR4/7 appear to show reasonable evidence of their ability to assess FCR in patients with both localized and metastatic cancer. Our calculations were clear for the total sample. Unfortunately, close examination of the psychometric criteria by subgroups was not feasible. This was due, possibly, to the relatively small subgroup sample sizes (n = 100). Such small subgroups tend to present statistical challenges in convergence and are sensitive to restrictive levels of degrees of freedom. Future studies with larger samples are recommended. Similar findings were noted in previous studies that have analyzed the psychometric data of these measures, including the original studies validating these measures, and other translations (e.g., Chinese, Danish, Dutch, Spanish). In general, these brief measures possessed a high reliability coefficient, with psychometrics properties confirming their cross-cultural validity [9,11,15,16,22-25]. Some of these studies were performed among a disease-specific populations (e.g., melanoma, colorectal, gynecological cancers) and patients with localized disease. Notably, no other clinical (treatment, time since diagnosis) or demographic (age, gender, marital status) characteristics have been considered in the assessment of these measures.

The confirmatory factor analyses supported the unidimensional nature of each scale. Some caution is required with the relatively small sample, as raised already, to interpret the fit indices. We are aware that the RMSEA index with the FCR7 analysis was marginal in accepting

the measurement model fit, however the CFI and SRMR values were favorable. It is worth noting with small degrees of freedom that the RMSEA can be inflated and unreliable [20].

A significant proportion of patients (32.0% - 43.0%) reported moderate to severe FCR. Higher levels of FCR were associated with younger age (whole sample) and female gender (those patients with metastatic cancer). We are aware that interpretation of cut-off values requires caution across translations and recommend further study to establish country specific estimated values. These characteristics have been noted as important risk factors for FCR [16]. Our findings extend this research and suggests that these characteristics may transcend cultural factors and may help guide health care providers to identify patients at risk of FCR [6,26]. Marital status, level of education, time since diagnosis were not associated with FCR. There remains no consensus regarding the role of these characteristics as risk factors for FCR, although a recent meta-analysis did suggest that lower level of education may be associated with moderate to severe FCR, while inconsistent associations have been found for type of cancer, and time since diagnosis [6,26]. Finally, patients with metastatic disease reported significantly higher rates of moderate to severe FCR compared with patients with localized breast cancer. This finding emphasizes the emotional burden that patients with incurable cancer can face.

In our survey of patients' perspectives of the study measures, simple and brief scales appeared more acceptable. A significant proportion of patients (41.4%) did not express a preference, 26.7% of patients stated that they liked both measures, and 14.7% included suggestions or noted challenges to completing the scales. Thus, it appears that either measure is reliable and acceptable to Portuguese-speaking Brazilian patients. Generally, patients were able to understand both measures (FCR4/7 and FCRI-SF) and the use of the term FCR to characterize their fear. A small proportion (14.7%) of patients suggested additional items they felt better characterized their own fear from all measures.

The content analysis of open-ended question responses mentioned that there were some questions that were difficult to answer (FCR4/7= 1 item and FCRI-SF = 4 items), with several participants feeling these items did not reflect their experience. Interestingly, these items were not necessarily identified as psychometrically less strong. For example, item 6 of the FCR7 asks about physical signs of possible recurrence. This gave the lowest item-total correlation (r = .53) but was not identified as an item needing improvement in open-ended question responses. There were no obvious differences among patients with localized or metastatic cancer regarding these questions. Patients also provided suggestions to improve the assessment of FCR. For example, items should state if they are assessing fear of cancer recurrence or progression, thus providing clarification for those with metastatic disease. This finding aligns with previous studies that examined the equivalence of both constructs and noted that it was not appropriate to treat these terms as synonymous [5]. This approach will enable us to better understand the fear experienced by these two different groups of patients.

Despite our novel findings, this study has several limitations. Firstly, the relatively small sample size included in this study may impact the ability to generalize findings to the broader population, although we did recruit patients from the 5 states across the country. Second, we employed maximum likelihood estimation for our confirmatory factors analyses which may reduce factor loadings with items exhibiting skewness and hence some result in some bias. Third, we did not assess patients with other validated measures of FCR, thus future research could examine the relationship between our findings and other measures in the literature, as well as the association between FCR and emotional symptoms (e.g., anxiety and depression) [9,11,16]. Fourth, this was a cross-sectional study, and thus did not permit the longitudinal trajectory of FCR to be assessed, as well as the test-retest reliability of the measures. Fifth, we did not collect information regarding functional status and patients' perception of prognosis, which could be used

to better characterize FCR across groups. Finally, in line with the objectives of this study, we assessed the construct validity of measures, rather than investigating the extent to which the measured constructs of interest correlated with or diverged from other similar constructs (convergent and divergent validity).

In summary, our findings suggest that the Portuguese versions of the FCRI-SF and FCR4/7 possess sufficient validity in the assessment of FCR among Brazilian patients with localized or metastatic cancer. Importantly, patients found both measures acceptable and the scales were able to provide meaningful information regarding the severity of FCR. Future studies are needed to identify risk factors associated with FCR and guide the development of effective and targeted interventions for patients globally.

REFERENCES

1. S. Simard, B. Thewes, G. Humphris, M. Dixon, C. Hayden, S. Mireskandari, G. Ozakinci, Fear of cancer recurrence in adult cancer survivors: a systematic review of quantitative studies. J Cancer Surviv. 7 (2013) 300-322. https://doi.org/10.1007/s11764-013-0272-z

2. P. Butow, J. Shaw, L. Vaccaro, L. Sharpe, H. Dhillon, B. Smith, PoCoG FRC Interest Group, A research agenda for fear of cancer recurrence: a Delphi study conducted in Australia. Psycho-Oncology. 28 (2019) 989-996. https://doi.org/10.1002/pon.5048

3. S. Lebel, G. Ozankinci, G. Humphris, B. Mutsaers B, B. Thewes, J. Prins, A. Dinkel, P. Butow, University of Ottawa Fear of Cancer Recurrence Colloquium attendees, From normal response to clinical problem: Definition and clinical features of fear of cancer recurrence. Support Care Cancer. 24 (2016) 3265-3268. https://doi.org/10.1007/s00520-016-3272-5

4. B. Mutsaers, P. Butow, A. Dinkel, G. Humphris, C. Maheu, G. Ozakinci, J. Prins, L. Sharpe, A.B. Smith, B. Thewes, S. Lebel, Identifying the key characteristics of clinical fear of cancer recurrence: An international delphi study. Psycho-Oncology. 29 (2020) 430-436. https://doi.org/10.1002/pon.5283

5. D. Coutts-Bain, L. Sharpe, P. Pradhan, H. Russell, L.C. Heathcote, D. Costa, Are fear of cancer recurrence and fear of progression equivalent constructs? Psycho-Oncology. 31 (2022) 1381-1389. https://doi.org/10.1002/pon.5944

6. Y. L. Luigjes-Huizer, N.M. Tauber, G. Humphris, N.A. Kasparian, W.W.T. Lam, S. Lebel, S. Simard, A.B. Smith, R. Zachariae, Y. Afiyanti, K. J. L. Bell, J. A. E. Custers, N. J de Wit, P.L. Fisher, J. Galica, S. N. Garland, C. W. Helsper, M.M. Jeppesen, J. Liu, R. Mititelu, E.M. Monninkhof, L. Russell, J. Savard, A.E.M. Speckens, S.J van Helmondt, S. Vatandoust, N. Zdenkowski, M.L. van der Lee, What is the prevalence of fear of cancer recurrence in cancer

survivors and patients? A systematic review and individual participant data meta-analysis. Psycho-Oncology. 31 (2022) 879-892. https://doi.org/10.1002/pon.5921

7. K. Anderson, A.B. Smith, A. Diaz, J. Shaw, P. Butow, L. Sharpe, A. Girgis, S. Lebel, H. Dhillon, L. Burhansstipanov, B. Tighe, G. Garvey, A systematic review of fear of cancer recurrence among indigenous and minority peoples. Front Psychol. 3 (2021) 621850. https://doi.org/10.3389/fpsyg.2021.621850

8. B. Thewes, P. Butow, R. Zachariae, S. Christensen, S. Simard, C. Gotay, Fear of cancer recurrence: a systematic literature review of self-report measures. Psycho-Oncology. 21 (2012) 571-587. https://doi.org/10.1002/pon.2070

9. S. Simard, J. Savard, Screening and comorbidity of clinical levels of fear of cancer recurrence. J Cancer Surviv. 9 (2015) 481-491. https://doi.org/10.1007/s11764-015-0424-4

10. A.B. Smith, D. Costa, J. Galica, S. Lebel, N. Tauber, S.J. van Helmondt, R. Zachariae, Spotlight on the Fear of Cancer Recurrence Inventory (FCRI). Psychol Res Behav Manag. 13 (2020) 1257-1268. https://doi.org/10.2147/PRBM.S231577

11. G.M. Humphris, E. Watson, M. Sharpe, G. Ozakinci, Unidimensional scales for fears of cancer recurrence and their psychometric properties: the FCR4 and FCR7. Health Qual Life Outcomes. 16 (2018) 30. https://doi.org/10.1186/s12955-018-0850-x

12. P. Butow, L. Sharpe, B. Thewes, J. Turner, J. Gilchrist, J. Beith, Fear of Cancer Recurrence: A Practical Guide for Clinicians. Oncology (Williston Park). 32 (2018) 32-38.

13. N.M. Tauber, M.S. O'Toole, A. Dinkel, J. Galica, G. Humphris, S. Lebel, C. Maheu, G. Ozakinci, J. Prins, L. Sharpe, A. B. Smith, B. Thewes, S. Simard, R. Zachariae, Effect of psychological intervention on fear of cancer recurrence: A systematic review and meta-analysis. J Clin Oncol. 37 (2019) 2899-2915. https://doi.org/10.1200/JCO.19.00572

14. D.E. Beaton, C. Bombardier, F. Guillemin, M.B. Ferraz, Guidelines for the process of cross-cultural adaptation of self-report measures. Spine. 25 (2000) 3186-3191. https://doi.org/10.1097/00007632-200012150-00014

15. S. Simard, J. Savard, Fear of Cancer Recurrence Inventory: development and initial validation of a multidimensional measure of fear of cancer recurrence. Support Care Cancer. 17 (2009) 241-251. https://doi.org/10.1007/s00520-008-0444-y

16. J.E. Fardell, G. Jones, A.B. Smith, S. Lebel, B. Thewes, D. Costa, K. Tiller, S. Simard, A. Feldstain, S. Beattie, M. McCallum, Conquer Fear authorship group, P. Butow, Exploring the screening capacity of the Fear of Cancer Recurrence Inventory–Short Form for clinical levels of fear of cancer recurrence. Psychooncology. 27 (2018) 492-499. https://doi.org/10.1002/pon.4516

17. T.A. Brown, Confirmatory factor analysis for applied research. Guilford Press, New York, 2006.

18. A. Acock, Discovering structural equation modelling using STATA. Revised Edition. Texas, College Station, Stats Press, Stata Corp LP, 2013.

19. D. Hooper, J. Coughlan, M.R. Mullen. Structural equation modelling: Guidelines for determining model fit. Electronic journal of business research methods. 6 (2008) 53-60.

20. D. A. Kenny, B Kaniskan, D. B. McCoach. The performance of RMSEA in models with small degrees of freedom. Sociological Methods & Research. 44(2015) 486-507.

21. M. Rhemtulla, P. É. Brosseau-Liard, V. Savalei. When can categorical variables be treated as continuous? A comparison of robust continuous and categorical SEM estimation methods under suboptimal conditions. Psychological methods. 17(2012).

22. X. Luo, W. Li, Y. Chen, H. Sun, G. Humphris, T. Liu, J. Zhang, Y. Yang, B. Zhang, Fear of Recurrence in Chinese Cancer Patients: Prevalence, Correlates, and Network Analysis. Front Psychiatry. 13 (2022) 803543. https://doi.org/10.10.3389/fpsyt.2022.803543

23. A. Iglesias-Puzas, V. García-González, A. Conde-Taboada, E. López-Bran, Fear of cancer recurrence in patients with non-metastatic melanoma: Spanish validation and disease-related factors. Australas J Dermatol. 2022; Early View. https://doi.org/10.1111/ajd.13907

24. S.J. van Helmondt, M.L. van der Lee, J. de Vries, Translation and validation of the Dutch version of the Fear of Cancer Recurrence Inventory (FCRI-NL). J Psychosom Res. 102 (2017) 21-28. https://doi.org/10.1016/j.jpsychores.2017.09.001

25. I.H. Jakobsen, M.M. Jeppesen, S. Simard, H.V. Thaysen, S. Laurberg, T. Juul T, Initial validation of the Danish version of the Fear of Cancer Recurrence Inventory (FCRI) in colorectal cancer patients. J Cancer Surviv. 12 (2018) 723-732. https://doi.org/10.1007/s11764-018-0709-5

26. C.D. Bergerot, E.J. Philip, P.G. Bergerot, N. Siddiq, S. Tinianov, M. Lustberg, Fear of cancer recurrence or progression: What is it and what can we do about it? ASCO Ed Book. 42 (2022) 18-27. https://doi.org/10.1200/EDBK_100031

Accepted refereed manuscript of: Bergerot CD, Ferreira LN, Molina LNM, Pagung LB, Pedersen BdS, de Andrade TG, Machado RHI, Freitas ANdS, Barreto LHCT, de Araujo LL, Tumeh IBRG, Vieira NBS, Lee D, Philip EJ, Neto JNM, Buso MM, Simard S, Ozakinci G, Humphris G, Bergerot PG & Smith AB (2023) Fear of cancer recurrence among Brazilian patients with cancer: Translation and cultural adaptation of FCR4/7 and FCRI-SF measures. *Journal of Psychosomatic Research*, 165. https://doi.org/10.1016/j.jpsychores.2022.111125

Table 1. Patients' characteristics (N=200).

Characteristics	Localized Cancer (n=100)	Metastatic Cancer (n=100)	Total (N=200)
Gender [N(%)]			
Male	1 (1.0)	41 (41.0)	42 (21.0)
Female	99 (99.0)	59 (59.0)	158 (79.0)
Age [Median (min-max)]	53.5 (25-88)	61.5 (19-87)	58.00 (19-88)
Marital Status [N(%)]			
Single	8 (8.0)	9 (9.0)	17 (8.5)
Married	68 (68.0)	69 (69.0)	137 (68.5)
Divorced	17 (17.0)	11 (11.0)	28 (14.0)
Widowed	7 (7.0)	11 (11.0)	18 (9.0)
Education [N(%)]			
Elementary School	1 (1.0)	7 (7.0)	8 (4.0)
High School	29 (29.0)	35 (35.0)	64 (32.0)
College Degree	68 (68.0)	47 (47.0)	115 (57.5)
Beyond College	2 (2.0)	11 (11.0)	13 (6.5)
Type of Cancer [N(%)]			
Breast	100 (100)	23 (23.0)	123 (61.5)
Genitourinary (kidney)	-	23 (23.0)	23 (11.5)
Gastrointestinal	-	23 (23.0)	23 (11.5)
Gynecological	-	12 (12.0)	12 (6.0)
Lung	-	11 (11.0)	11 (5.5)
Genitourinary (prostate and bladder)	-	4 (4.0)	4 (2.0)
Sarcoma	-	2 (2.0)	2 (1.0)
Hematological	-	2 (2.0)	2 (1.0)
Disease Stage [N(%)]			
I	44 (44.0)	-	44 (22.0)
II	45 (45.0)	-	45 (22.5)
III	11 (10.0)	23 (23.0)	34 (17.0)
IV	-	77 (77.0)	77 (38.5)
Year since Diagnosis [Median(min-max)]	3.0 (1-20)	1.0 (0-19)	2.0 (0-20)
FCR7			
Moderate FCR	26 (26.0)	25 (25.0)	51 (25.5)
Severe FCR	2 (2.0)	11 (11.0)	13 (6.5)
FCRI-SF			
Moderate FCR	32 (32.0)	37 (37.0)	69 (34.5)
Severe FCR	6 (6.0)	11 (11.0)	17 (8.5)

Table 2. Psychometric analysis for FCR4, FCR7 and FCRI-SF

FCR4 items	Q1	Q2	Q3	Q4	Total
1. I am afraid that my cancer may recur	1.000	.769*	.644*	.548*	.821*
2. I am worried or anxious about the possibility of cancer recurrence		1.000	.730*	.611*	.831*
3. How often have you worried about the possibility of getting cancer again			1.000	.570*	.774*
4. I get waves of strong feelings about the cancer coming back				1.000	.799*
Total Score					1.000

Note. *Pearson's correlation P<0.001 (2-tailed); N=200

FCR7 items	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Total**
1. I am afraid that my cancer may recur	1.000	.769*	.644*	.548*	.602*	.300*	.638*	.821*
2. I am worried or anxious about the possibility of cancer recurrence		1.000	.730*	.611*	.672*	.368*	.556*	.831*
3. How often have you worried about the possibility of getting cancer again			1.000	.570*	.689*	.361*	.476*	.774*
4. I get waves of strong feelings about the cancer coming back				1.000	.680*	.457*	.582*	.799*
5. I think about the cancer returning when I didn't mean to					1.000	.355*	.532*	.803*
6. I examine myself to see if I have physical signs of cancer						1.000	.351*	.532*
7. To what extent does worry about getting cancer again spill over or intrude on your thoughts and activities							1.000	.840*
Total Score								1.000

Note. *Pearson's correlation P<0.001 (2-tailed); N=200

Accepted refereed manuscript of: Bergerot CD, Ferreira LN, Molina LNM, Pagung LB, Pedersen BdS, de Andrade TG, Machado RHI, Freitas ANdS, Barreto LHCT, de Araujo LL, Tumeh IBRG, Vieira NBS, Lee D, Philip EJ, Neto JNM, Buso MM, Simard S, Ozakinci G, Humphris G, Bergerot PG & Smith AB (2023) Fear of cancer recurrence among Brazilian patients with cancer: Translation and cultural adaptation of FCR4/7 and FCRI-SF measures. *Journal of Psychosomatic Research*, 165. https://doi.org/10.1016/j.jpsychores.2022.111125

FCRI-SF items	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Total
1. I am worried or anxious about the possibility of cancer recurrence	1.000	.735*	.409*	.626*	.336*	.400*	.684*	.670*	.545*	.817*
2. I am afraid of cancer recurrence	1.00	.435*	.562*	.291*	.379*	.668*	.635*	.475*	.784*	
3. I believe it is normal to be worried or anxious about the possibility of cancer recurrence		1.000	.461*	.216*	.295*	.385*	.281*	.314*	.592*	
4. When I think about the possibility of cancer recurrence, this triggers other unpleasant thoughts or images (such as death, suffering, the consequences for my family)			1.000	.271*	.339*	.629*	.469*	.397*	.719*	
5. I believe that I am cured and that the cancer will not come back				1.000	.559*	.370*	.310*	.291*	.605*	
6. In your opinion, are you at risk of having a cancer recurrence?					1.000	.512*	.405*	.403*	.673*	
7. How often do you think about the possibility of cancer recurrence?						1.000	.702*	.611*	.839*	
8. How much time per day do you spend thinking about the possibility of cancer recurrence?							1.000	.610*	.760*	
9. How long have you been thinking about the possibility of cancer recurrence?								1.000	.707*	
Total									1.000	

Note. * Pearson's correlation p<.001 (2-tailed); N=200

Table 3. CFA factor loadings, correlated errors, fit indices, and reliability coefficients for all FCR scales

		FCR4	FCR7	FCRI-SF
Factor loadings				
	Q1	.827	.741	.815
	Q2	.922	.833	.772
	Q3	.794	.813	.479
	Q4	.673	.773	.726
	Q5		.832	.406
	Q6		.469	.530
	Q7		.658	.867
	Q8			.815
	Q9			.679
Correlated errors:	Item pairs‡			
	Q1,Q2		.404	
	Q1,Q7		.291	
	Q1,Q2			.283
	Q4,Q8			.304
	Q5,Q6			.448
Fit Indices from CFA models				
	Chi Square (df)	1.921(2)	35.66(12)	41.73(24)
	p-value	.383	.0004	.014
	CFI	1.00	.971	.980
	RMSEA (95%CIs)	.0001	.099	.061
	lower bound	.000	.063	.027
	upper bound	.14	.138	.091
	SRMR	.0001	.036	.037
Internal Consistency	Cronbach's alpha (95%CIs)	.879	.894	.887
	lower bound	.855	.874	.866
	upper bound	.904	.914	.908

Note. ‡ No correlated errors for the FCR4 scale (i.e., modification indices <4)

Table 4. Patients' perspectives regarding the measures (N=75)

Both measures	'Both measures are good. It is hard to pick one' 'Both are similar. I usually tend to choose the brief questionnaire' 'I like the items #1, 2, 3, 4, 6 and 7 from the FCR4/7, and the items #1, 2 and 7 from the FCRISF. Maybe those items will make the perfect measure'	26.7%
FCR4/7	'I am worried about my future. The FCR4/7 assess this issue' 'The last question from the FCR4/7 summarize everything' 'Simple and short. I like this one'	41.3%
FCRISF	'This questionnaire is more comprehensive' 'I like the item about my risk of having a cancer recurrence' 'This questionnaire better explore my fear'	17.3%
Difficulties and suggestions	'The FCR4/7 has some items that are not related with what I am experiencing. Items should also be developed for those living with metastatic cancer' 'I had a hard time answering the last 4 items from the FCRISF. It should have an intermediate option' 'Answering to the FCRISF made me feel more anxious' 'It was hard to answer to the item #7 (FCRISF) and the item #3 (FCR4/7). I think about it just when I have the follow-up appointment' 'These measures should have an option of not responding to all items. For example, I'm not worried about recurrence' 'Measures should assess the fear of recurrence before the follow-up appointment' 'Some items represent what I am feeling (FCR4/7 #1,2,6,7 and FCRISF #1,2,6,7) and other ones I've never experienced (FCR4/7 #3 and FCRISF #5,7,8,9)	14.7%