Measurement of Cancer-Related Fatigue: Dimensional Structure and Internal Consistency of the Brazilian Version of The EORTC QLQ-FA12 Instrument

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Aferição da Fadiga Relacionada ao Câncer: Estrutura Dimensional e Consistência Interna da Versão Brasileira do Instrumento EORTC QLQ-FA12

Evaluación de la Fatiga Relacionada con el Cáncer: Estructura Dimensional y Consistencia Interna de la Versión Brasileña del Instrumento EORTC QLQ-FA12

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ABSTRACT

Introduction: European studies have demonstrated the three-dimensional structure and adequate reliability of the EORTC QLQ-FA12 for assessing cancer-related fatigue. **Objective:** To evaluate the dimensional structure and internal consistency of the Brazilian version of the EORTC QLQ-FA12. **Method:** A cross-sectional study with 278 patients at a High-Complexity Oncology Care Center located in Rio de Janeiro, Brazil. Confirmatory factor analysis was performed using the Weighted Least Squares Mean and Variance Adjusted estimator and polychoric correlation matrices. Exploratory structural equation models were tested using confirmatory factor analysis methods and *geomin* oblique rotation. The Comparative Fit Index, Tucker-Lewis Index, and Root Mean Square Error of Approximation (RMSEA) were used to evaluate model fit. Internal consistency was assessed through composite reliability, and correlations between dimensions were examined to investigate discriminant factorial validity. **Results:** The confirmatory factor analysis of the three-dimensional structure, despite a borderline RMSEA, showed overall good statistical fit, with factor loadings ranging from 0.608 to 0.873 in the original dimensions, adequate internal consistency, and acceptable discriminant validity. However, in exploratory structural equation models, this structure presented cross-loadings as well as a borderline RMSEA. Internal consistency was considered adequate, and correlations between dimensions were acceptable. **Conclusion:** The Brazilian version of the EORTC QLQ-FA12 appears to be three-dimensional, with all items coherently representing the construct of cancer-related fatigue.

Key words: Neoplasms/complications; Fatigue; Evaluation of Research Programs and Tools.

RESUMO

Introdução: Estudos europeus atestaram a tridimensionalidade e a apropriada confiabilidade do instrumento EORTC QLQ-FA12 para aferição da fadiga relacionada ao câncer. **Objetivo:** Avaliar a estrutura dimensional e a consistência interna da versão brasileira do EORTC QLQ-FA12. **Método:** Estudo transversal com 278 pacientes em um Centro de Assistência de Alta Complexidade em Oncologia localizado no Rio de Janeiro, Brasil. Realizou-se análise fatorial confirmatória empregando o estimador *Weighted Least Squares Mean and Variance Adjusted* e matrizes de correlações policóricas. Testaram-se modelos de equação estrutural exploratórios seguindo métodos de análise fatorial confirmatória e uso da rotação oblíqua *geomin*. Os *Comparative Fit Index*, Tucker-Lewis *Index* e *Root Mean Square Error of Approximation* (RMSEA) avaliaram a qualidade do ajuste do modelo. A consistência interna foi avaliada pela confiabilidade composta e correlações entre dimensões foram examinadas para investigar validade fatorial discriminante. **Resultados:** A análise fatorial confirmatória da estrutura tridimensional, mesmo com o RMSEA limítrofe, demonstrou bom ajustamento estatístico geral, cargas fatoriais variando de 0,608 a 0,873 nas dimensões originais, adequada consistência interna e aceitável validade fatorial discriminante. Porém, nos modelos de equação estrutural exploratórios, essa estrutura exibiu cargas fatoriais cruzadas, além de um RMSEA fronteiriço. A consistência interna foi considerada adequada e a correlação entre dimensões, aceitável. **Conclusão:** A versão brasileira do EORTC QLQ-FA12 parece ser tridimensional, com todos os itens representando coerentemente o construto fadiga relacionada ao câncer.

Palavras-chave: Neoplasias/complicações; Fadiga; Avaliação de Programas e Instrumentos de Pesquisa.

RESUMEN

Introducción: Estudios europeos han certificado la tridimensionalidad y la adecuada confiabilidad del instrumento EORTC QLQ-FA12 para evaluar la fatiga relacionada con el cáncer. **Objetivo:** Evaluar la estructura dimensional y la consistencia interna de la versión brasileña del EORTC QLQ-FA12. **Método:** Estudio transversal con 278 pacientes en un Centro de Atención Oncológica de Alta Complejidad ubicado en Río de Janeiro, Brasil. Se llevó a cabo un análisis factorial confirmatorio utilizando el estimador *Weighted Least Squares Mean and Variance Adjusted* y matrices de correlación policórica. Se probaron modelos exploratorios de ecuaciones estructurales utilizando métodos de análisis factorial confirmatorio y rotación oblicua *geomin*. El *Comparative Fit Index*, *Tucker-Lewis Index* y el *Root Mean Square Error of Approximation* (RMSEA) evaluaron la calidad del ajuste del modelo. La consistencia interna se evaluó mediante la confiabilidad compuesta y se examinaron las correlaciones entre dimensiones para investigar la validez factorial discriminante. **Resultados:** El análisis factorial confirmatorio de la estructura tridimensional, aun con un RMSEA limítrofe, demostró un buen ajuste estadístico general, con cargas factoriales que oscilaron entre 0,608 y 0,873 en las dimensiones originales, consistencia interna adecuada y validez factorial discriminante aceptable. Sin embargo, en los modelos exploratorios de ecuaciones estructurales, esta estructura presentó cargas factoriales cruzadas, así como un RMSEA limítrofe. La consistencia interna se consideró adecuada y la correlación entre dimensiones, aceptable. **Conclusión:** La versión brasileña del EORTC QLQ-FA12 parece ser tridimensional y todos los ítems representan de manera coherente el constructo de fatiga relacionada con el cáncer.

Palabras clave: Neoplasias/complicaciones; Fatiga; Evaluación de Programas e Instrumentos de Investigación.

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INTRODUCTION

Cancer-related fatigue is a subjective, persistent, and anguishing feeling of physical, emotional, and/or cognitive tiredness related to the disease or its treatment[1], with an overall prevalence of 52%, according to a meta-analysis[2]. This symptom, in addition to being one of the most common and debilitating both during and after oncological treatment, since it does not properly alleviate with rest, causes harmful effects to patients' physiological, psychological, mental, and social activities, which can significantly compromise their quality of life[1].

Since the assessment and management of cancer-related fatigue are key both for therapeutic decisions and clinical outcomes, its measurement instruments must be encompassing, precise, and reliable[3]. To measure cancer-related fatigue, the European Organization for Research and Treatment of Cancer (EORTC) developed the EORTC Quality of Life Questionnaire Fatigue Module 13 items (QLQ-FA13)[4], renamed EORTC QLQ-FA12 (FA12) after a new psychometric analysis, which relocated one item and excluded another[5]. Since then, more studies[6-8] have confirmed its three-dimensional ability[5] and appropriate reliability[5].

FA12 results from a conceptual model of cancer-related fatigue that investigates the occurrence of symptoms or problems during the week before its application, distributed in three dimensions: physical, emotional, and cognitive[4,5]. The first is composed of five items, the second of three, and the last of two, with four answer options that map the intensity of the investigated symptoms/problems[5] (Chart 1). The last two items of the instrument are not part of any dimension because they respectively assess the inference of fatigue in daily activities and the social consequences of this phenomenon. Its applicability is wide, as it can be employed in any step of patient follow-up, regardless of the type of tumor, staging, and intention of the antineoplastic treatment[4,5].

Viana et al.[9], following the universalistic model proposed by Herdman et al.[10], conducted the first steps in the transcultural adaptation of FA12 to be used in Brazil, that is, the conceptual, semantic, operational, and item equivalence. They concluded that the Brazilian version of the instrument is equivalent to the original in English, being well understood through interviews. Silva et al.[11] advanced in the process of transcultural adaptation of the FA12 by assessing a significant aspect of the equivalence of measurement, the test-retest reliability, which demonstrated stable responses in a 7-to-15-day interval between one interview and the other, with estimates varying between good and excellent (*kappa* = 0.66 to 0.80).

Since the transcultural adaptation process of FA12 for its use in Brazil must continue to follow rigorous methodological steps aiming at functional equivalence, two other important aspects of measurement equivalence of its Brazilian version[9] were assessed in the present study: the dimensional structure and internal consistency.

METHOD

Cross-sectional study developed at a High-Complexity Oncology Center linked to the National Health System (SUS) and located in the homonymous capital of Rio de Janeiro State, Brazil, from September 2023 through January 2024. Regardless of treatment intention and regime, the study included literate patients with a confirmed cancer diagnosis, aged ≥18 years, and with a preserved capacity for verbal communication. The approach/selection of patients did not follow probabilistic criteria, being made in several outpatient clinics and nursing wards by two trained nurses who also conducted interviews and collected data from medical charts. The interviews were guided by a questionnaire that contained, in addition to the Brazilian version of the FA12[9] instrument, sociodemographic (sex, age, education), diagnosis (conclusion and clinical staging[12]), and treatment (type) characterization variables.

Regarding statistical analyses, the three-dimensional structure of FA12 was assessed first, by employing the Weighted Least Squares Mean and Variance Adjusted estimator and polychoric correlation matrices through confirmatory factor analysis; factor loadings (λ)>0.40 were considered satisfactory[13]. The model fit quality was examined using the incremental fit indexes Comparative Fit Index (CFI) >0.95[13] and Tucker-Lewis Index (TLI)>0.95[13] and the parsimonious fit index Root Mean Square Error of Approximation (RMSEA) <0.08[14] and its 90% confidence interval (CI 90%), whose superior limit indicates an unfit model and consequent rejection when >0.10[15].

Then, the dimensional structure of FA12 was reassessed using a sequence of exploratory structural equations model, following methods employed in confirmatory factor analyses and the use of geomin oblique rotation[16]. The model was considered fit if the items did not show crossed λ, that is, showed (i) λ>0.40 in the primarily conceived dimension, (ii) λ<0.30 in an alternative dimension, and (iii) a difference between them >0.20, thus meeting the rule 0.40-0.30-0.20[14].

The internal consistency of FA12 was calculated using composed reliability, considered satisfactory when ≥0.70[13]. Correlations between its dimensions were explored, considering values >0.85 as suggestive of absence of discriminating factor validity[13]. Moreover, potential residual correlations were observed between its items and

Chart 1. Brazilian version of the EORTC QLQ-FA12

Dimension	***Durante a última semana* (During the past week)**	***Não* (Not at all)**	***Um pouco* (A bit)**	***Moderadamente* (Quite a bit)**	***Muito* (Very much)**
Physical	*1. Você se sentiu sem energia?* (Have you lacked energy?)	1	2	3	4
	2. Você se sentiu exausto(a)? (Have you felt exhausted?)	1	2	3	4
	3. Você se sentiu mais devagar do que o normal? (Have you felt slowed down more than normal?)	1	2	3	4
	4. Você se sentiu sonolento(a) durante o dia? (Did you feel sleepy during the day?)	1	2	3	4
	5. Você teve dificuldade para começar as coisas? (Did you have trouble getting things started?)	1	2	3	4
Emotional	*6. Você se sentiu sem coragem?* (Did you feel discouraged?)	1	2	3	4
	7. Você se sentiu desamparado(a)? (Did you feel helpless?)	1	2	3	4
	8. Você se sentiu frustrado(a)? (Did you feel frustrated?)	1	2	3	4
Cognitive	*9. Você teve dificuldade para pensar com clareza?* (Did you have trouble thinking clearly?)	1	2	3	4
	10. Você se sentiu confuso(a)? (Did you feel confused?)	1	2	3	4
	11. O cansaço atrapalhou as suas atividades diárias? (Did tiredness interfere with your daily activities?)	1	2	3	4
	12. Você sentiu que o seu cansaço não é (foi) compreendido pelas pessoas próximas a você? (Did you feel that your tiredness is (was) not understood by the people who are close to you?)	1	2	3	4

Source: Viana et al.[9]

those with different dimensions of those specified by the primary conceptual model when the modification indexes (MI) were >10, which indicated content redundancy[17].

All the statistical analyses were conducted in the Mplus[18] software, version 7.1. As in previous studies[5-8], only the first 10 items of the instrument were analyzed because the latter assess the interference of cancer-related fatigue in daily activities (item 11) and the social consequences (item 12) of this symptom[4,5].

The present study was approved by the Research Ethics Committee (CEP) of the National Cancer Institute, approval report number 863,339 (CAAE (submission for ethical review): 33237314.2.0000.5274), according to Resolution N. 466/12[19] of the National Health Council (CNS), and all the participants signed a Free and Informed Consent Form (FICF).

RESULTS

A total of 278 patients participated in the study. They had a mean age of 56 (±14) years, mostly male (55.04%), with complete high school/undergraduate education (47.48%), receiving some kind of treatment (82.01%), with chemotherapy being the most frequent (66.91%). The most common diagnoses were lymphomas (12.59%), rectum cancer (11.87%), sigmoid colon cancer (8.99%), bronchi/lungs cancer (7.91%), and leukemias (7.19%). A total of 70.90% of medical charts had no information on clinical staging; among those in which it was documented, stage IV (13.70%) stood out.

The confirmatory factor analysis of the FA12 three-dimensional structure showed every item with λ ranging from 0.608 to 0.873 in the original dimensions. The

incremental fit indexes of this model were satisfactory, but the parsimonious fit index and respective superior limit of its 90%CI were not, despite being borderline (Table 1). Correlations between dimensions were equal to 0.579 (Physical ↔ Cognitive), 0.690 (Physical ↔ Emotional), and 0.734 (Emotional ↔ Cognitive), indicating acceptable discriminant factor validity. The reliability, composed of the physical, emotional, and cognitive dimensions, showed high and satisfactory values (respectively, 0.880, 0.840, and 0.802), demonstrating the adequate internal consistency of the instrument. The MI suggested residual correlations of items 6 and 7 with the physical dimension, respectively, equal to 36.024 and 12.648.

The exploratory structural equation models showed that the three-dimensional structure was the only one to present satisfactory fit indexes, except for the borderline RMSEA 90%CI. However, items 4, 5, 6, 7, 9, and 10 showed crossed λ (Table 2), and the MI suggested residual correlations between the item pairs 4 ↔ 5 (MI=22.582) and 9 ↔ 10 (MI=36.721). The other dimensional structures tested in the exploratory models showed unsatisfactory fit indexes (Table 3).

DISCUSSION

This is the first study that assessed whether the dimensional structure of FA12 adequately captures the cancer-related fatigue construct in a non-European context. Even with the parsimonious fit index presenting borderline values, the confirmatory factor analysis of the three-dimensional structure of the Brazilian version of the instrument demonstrated a good general statistical fit, with high λ, adequate internal consistency, and acceptable discriminating validity between dimensions. However, in the exploratory structural equation models, the three-dimensional structure showed crossed λ, violating the 0.40-0.30-0.20 rule[14], despite the fit indexes being satisfactory, except for the borderline RMSEA 90%CI.

Although they have used appropriate techniques for assessing the validity of the structural construct of health measurement instruments[17] and met the recommendation of at least ten respondents per item[14], such findings must be cautiously interpreted. This is because validation studies conducted with small samples (n<200-300), like the present one, have a higher probability of compromising

Table 1. Results from the confirmatory factor analysis of the three-dimensional structure of the Brazilian version of the EORTC QLQ-FA12

Item	Dimension		
	Physical (λ)	Emotional (λ)	Cognitive (λ)
1. Você se sentiu sem energia? (Have you lacked energy?)	0.849		
2. Você se sentiu exausto(a)? (Have you felt exhausted?)	0.873		
3. Você se sentiu mais devagar do que o normal? (Have you felt slowed down more than normal?)	0.755		
4. Você se sentiu sonolento(a) durante o dia? (Did you feel sleepy during the day?)	0.608		
5. Você teve dificuldade para começar as coisas? (Did you have trouble getting things started?)	0.752		
6. Você se sentiu sem coragem? (Did you feel discouraged?)		0.869	
7. Você se sentiu desamparado(a)? (Did you feel helpless?)		0.834	
8. Você se sentiu frustrado(a)? (Did you feel frustrated?)		0.683	
9. Você teve dificuldade para pensar com clareza? (Did you have trouble thinking clearly?)			0.770
10. Você se sentiu confuso(a)? (Did you feel confused?)			0.865
Model fit quality indexes			
CFI[a]		0.967	
TLI[b]		0.953	
RMSEA[c] (90%CI)		0.085 (0.066-0.105)	

Captions: [a]CFI: Comparative Fit Index; [b]TLI: Tucker-Lewis Index; [c]RMSEA: Root Mean Square Error of Approximation.

Table 2. Results from the exploratory model of the three-dimensional structure of the Brazilian version of the EORTC QLQ-FA12

Item	Dimension		
	Physical (λ)	Emotional (λ)	Cognitive (λ)
1. Você se sentiu sem energia? (Have you lacked energy?)	0.919	0.007	0.096
2. Você se sentiu exausto(a)? (Have you felt exhausted?)	0.743	0.191	0.016
3. Você se sentiu mais devagar do que o normal? (Have you felt slowed down more than normal?)	0.768	0.030	0.242
4. Você se sentiu sonolento(a) durante o dia? (Did you feel sleepy during the day?)	0.551*	0.000	0.416*
5. Você teve dificuldade para começar as coisas? (Did you have trouble getting things started?)	0.587*	0.155	0.353*
6. Você se sentiu sem coragem? (Did you feel discouraged?)	0.395*	0.491*	0.009
7. Você se sentiu desamparado(a)? (Did you feel helpless?)	0.005	0.958*	0.325*
8. Você se sentiu frustrado(a)? (Did you feel frustrated?)	0.026	0.717	0.163
9. Você teve dificuldade para pensar com clareza? (Did you have trouble thinking clearly?)	0.022	0.669*	0.352*
10. Você se sentiu confuso(a)? (Did you feel confused?)	0.046	0.695	0.208
Model fit quality indexes			
CFI[a]	0.984		
TLI[b]	0.960		
RMSEA[c] (90%CI)	0.079 (0.053-0.105)		

Captions: *Factor cross-loadings; [a]CFI: Comparative Fit Index; [b]TLI: Tucker-Lewis Index; [c]RMSEA: Root Mean Square Error of Approximation.

Table 3. Quality fit index of other dimensional structures of the Brazilian version of the EORTC QLQ-FA12 tested in the exploratory models

Indexes	One-dimensional	Two-dimensional
CFI[a]	0.893	0.959
TLI[b]	0.862	0.930
RMSEA[c] (90%CI)	0.146 (0.129-0.164)	0.104 (0.084-0.126)

Captions: [a]CFI: Comparative Fit Index; [b]TLI: Tucker-Lewis Index; [c]RMSEA: Root Mean Square Error of Approximation.

stability and replicability of the revealed dimensional structure, especially in exploratory contexts[20].

Although the three-dimensional structure of FA12 had been confirmed in other studies[5-8], even when it had 13 items[4] or when applied to the general population[8], it was speculated that its psychometric properties should continue to be examined because it was maybe still in development. It is worth observing the MI that indicated residual correlations of items 6 and 7 with the physical dimension and suggested content redundancy in the pairs 4 ↔ 5 and 9 ↔ 10. Additionally, it is worth highlighting that, since the exclusion of an item from the cognitive dimension[5], FA12 does not meet the requirement of at least three items per dimension, which would confer it the due mapping of the growing intensity of the dimension content[21,22].

In light of this, we underscore that it is not convenient for a measurement instrument to have dimensions composed of fewer than three items, because they offer fewer degrees, limiting the confirmatory factor analysis ability to detect bad fits, residual correlations, and other problems of model specification[23]. Thus, the findings of the present study assert the relevance of examining the measurement properties of measuring instruments adapted to new cultural contexts, because, ultimately, it is the instrument's dimensional structure that indicates how to operationalize it in practice, avoiding inappropriate comparisons between studies that used it in different ways.[10].

Therefore, to reach functional equivalence, more studies that test the Brazilian version of FA12 are needed, either (re)assessing reliability, dimensional structure, and internal consistency, or examining criterion validity or construct validity, two important steps in the transcultural

adaptation of a health measurement instrument[24] to which it has not yet been submitted. Then, researchers and oncology professionals will have more evidence to base a decision about its use in the Brazilian cultural context, although a recent systematic review endorses that it is a valid, reliable, and useful tool to assess the quality of life of people with cancer-related fatigue[25].

It is worth highlighting that the internal consistency of the Brazilian version of FA-12 was considered satisfactory, indicating that all its items coherently represent the same latent construct, that is, cancer-related fatigue. The correlations between their dimensions were slightly elevated, but not enough to suggest the absence of discriminating factor validity. According to its brief psychometric history, FA-12 has appropriate internal consistency, since a multi-centric European study reported alpha Cronbach coefficients ranging from 0.79 (cognitive dimension) to 0.90 (physical dimension)[5]. In the face of correlations between dimensions equal to 0.62 (Physical ↔ Cognitive), 0.66 (Physical ↔ Emotional), and 0.58 (Emotional ↔ Cognitive), the same study found acceptable discriminant factor validity[5]. Two German studies described similar results: alpha Cronbach coefficients and correlations between dimensions oscillated, respectively, between 0.79 (cognitive dimension) and 0.93 (physical dimension) and between 0.50 (Physical ↔ Cognitive) and 0.66 (Physical ↔ Emotional) in one[6], while it oscillated between 0.732 (cognitive dimension) and 0.918 (physical dimension) and between 0.638 (Physical ↔ Cognitive) and 0.698 (Emotional ↔ Cognitive) in the other[7].

Despite not threatening its internal validity, given that the confirmatory factor analysis results confirm, in some way, the originally conceived[5] and, so far, confirmed[6-8] three-dimensionality of FA12, the small sample size is the main limitation of the present study. As previously mentioned, small samples (n<200-300) can influence stability and replicability of the revealed dimensional structure[20]. Thus, to more faithfully capture the dimensional structure of the Brazilian FA12 version, we recommend that further studies be conducted with a satisfactory sample size (n>500)[20]. Another limitation is the fact that the sample is non-probabilistic and homogeneous in what concerns the treatment received, which restricts its external validity.

It is worth clarifying that the expressive absence of information on clinical staging is related to the decision of collecting it from the medical chart only if the doctor had documented it before the patient received their first antineoplastic treatment (pre-treatment clinical classification[12]), as well as the fact that not every malignant tumor can be staged using the TNM system[12], like leukemias and lymphomas, for example. Thus, it does not mean such noble information is nonexistent from most consulted medical records, but rather that it reflects a methodological decision aligned with the general rules of the TNM system for the classification of malignant tumors proposed by the Union for International Cancer Control (UICC)[12]. Finally, it is worth highlighting that this does not compromise the validity of the present study, since only the first 10 items of FA12 were used to assess its dimensional structure and internal consistency, as it can be applied regardless of disease staging[4,5].

CONCLUSION

The Brazilian version of the FA-12 appears to be three-dimensional, in compliance with the instrument's original conception, with all items coherently representing the construct of cancer-related fatigue.

CONTRIBUTIONS

Rafael Tavares Jomar has contributed to the study design, data analysis and interpretation; and wording. Viviane Silva Viana has contributed to data acquisition, analysis, and interpretation; and wording. Valeska Maciel Martins has contributed to data acquisition and critical review. Camila Drumond Muzi and Raphael Mendonça Guimarães have contributed to the study design and planning; and critical review. All the authors approved the final version for publication.

DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

All the contents associated with the article are included in the manuscript.

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