

Original Article

Reproducibility of Functional Assessment of Cancer Therapy-Fatigue (FACT-F) Questionnaire for Cancer Patients

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Abstract

Objective: The objective of this study was evaluating the reproducibility in Portuguese of Functional Assessment of Cancer Therapy-Fatigue (FACT-F) questionnaire for cancer patients by applying it according to the test-retest method. **Material and Methods:** Subjects were 85 cancer patients with an average age of 51.0 years, being 56 (65.9%) women and 29 (34.1%) men. FACT-F questionnaire consists of 40 items, divided in five domains, and is applied for evaluating quality of life and fatigue in patients with cancer. We used as a measuring tool intraclass correlation coefficient values obtained from two measures of test-retest and scatter plot proposed by Bland-Altman. **Results:** In 36.5% of cases the questionnaire was self-administered, and in 63.5% of the cases read by an interviewer and filled after verbal answer. Intraclass correlation coefficient values found for the domains were: physical well-being 0.72; social/family well-being 0.91; emotional well-being 0.90; functional well-being 0.86; fatigue subscale 0.88, and for the FACT-F 0.91. The Bland-Altman plot showed to be adequate, since most points were within the limits of reliability. **Conclusions:** FACT-F questionnaire in Portuguese has good test-retest reproducibility in patients with different types of cancer, performance status and stages.

Keywords: Quality of life; fatigue; questionnaire; reproducibility

Introduction

Fatigue is highly prevalent, affecting about 94% of patients with cancer. Its frequency increases significantly during chemotherapy and radiotherapy¹ and has a great impact on the quality of life of oncologic patients.^{1,2}

Measuring fatigue has been widely used to evaluate the effects of treatments. It is also useful for studying new approaches and new ways of controlling symptoms, to improve the knowledge of doctors and to identify the necessities of the patients, aiming at the

development of more adequate care strategies.³

Cancer-related fatigue may be evaluated by specific one-dimensional or multidimensional instruments.¹ In a recent systematic review of the scientific literature, 14 fatigue-evaluating scales were found; the most common

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questionnaires were *Functional Assessment of Cancer Therapy Fatigue (FACT-F)*, *European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ C30)* (fatigue subscale) and it *Fatigue Questionnaire (FQ)*.⁴

FACT-F questionnaire has been used to evaluate symptoms resulting from cancer treatments such as chemotherapy^{5,6} and radiotherapy,⁷ as well as the efficiency, dosage and security of medicines for chemotherapy-induced anemia,^{8,9} in interventions involving exercises in patients with cancer and fatigue,¹⁰⁻¹² in complementary cancer therapy¹³ and in nursing interventions.¹⁴

FACT-F consists of a questionnaire with a total of 40 items, being 27 items the *Functional Assessment of Cancer Therapy-General (FACT-G)*, for evaluating global quality of life, and 13 specific items related to Fatigue.¹⁵ *FACT-F* is part of the measure system *Functional Assessment of Chronic Illness Therapy (FACIT)*, which comprises a collection of health-related quality of life questionnaires. These questionnaires were developed to be applied to patients with chronic diseases.¹⁶ All FACIT questionnaires are submitted to a standardized development with valid methodology that passes through five phases: (1) generation of the item, (2) revision and reduction of the item, (3) construction of the scale, (4) initial evaluation and (5) additional evaluation for the whole system measure.¹⁷ They are available in 45 languages, allowing the comparison of different populations, using a rigorous methodology of translation and back-translation, psychometric tests and cognitive interviews.¹⁶

FACT-G specifically was developed and validated to measure the quality of life in adult patients with cancer and is now in its 4 version.¹⁸ Its 27 items contemplate four domains: physical well-being, social/family well-being, emotional well-being and functional well-being. It is considered appropriate for patients with any type of cancer.¹⁹ *FACT-G* was conceived originally in English and submitted to a translation process into Portuguese, which included two translations, a reconciliation translation, a back-translation of the reconciled version and four independent revisions by bilingual expert. It was pre-tested in 19 cancer patients in Portugal and 30 in Brazil.^{20,21} However, the version in the Portuguese language was not validated for the Brazilian population. Thus, the use of *FACT-F* in Brazil requires to be validated and culturally adapted. The present study aims to evaluate the stability of version 4 of *FACT-F* questionnaire for the Portuguese language in its use with patients with cancer through the test-retest method.²²

Materials and Methods

Subjects selection

From September 2005 and February 2006, women and men with cancer treated with chemotherapy or hormone therapy in the outpatient department of Clinical Oncology of the Brazilian National Cancer Institute (INCA) were selected for the study. Patients were included with ages from 18 and 82 years and who were able to return to the Institution for consultations or treatment with other professionals, or to submit to examinations in a period from 3 to 14 days, which allowed the application of the retest. 85 patients were included in this study, a number higher than the minimum recommended sample size for test-retest reproducibility, which is at least 50 subjects.^{23,24}

Subjects were excluded who had more than one cancer diagnosis, were pregnant at diagnosis, and with a diagnosed psychiatric disease. In the end, 85 patients were included. The present study was approved by the Committee of Ethics of Research of the National Institute of Cancer. All patients signed the Term of Free and Informed Consent before being included in the research.

Instruments

Functional Assessment of Cancer Therapy - Fatigue (FACT-F)

We used version 4 of *FACT-F* with 40 items, including 27 of *FACT-G*, which evaluates specifically quality of life, and an additional domain with 13 specific items about Fatigue.¹⁵ The use of the questionnaire was authorized and made available by the authors in Portuguese language for this research. The instrument explores, as said, five domains: physical well-being, social/family well-being, emotional well-being and functional well-being and fatigue. The physical well-being domain has 7 items with scores from 0 to 28 points; social/family well-being, 7 items with score from 0 to 28 points; emotional well-being, 6 items with score from 0 to 24 points; functional well-being, 7 items with score from 0 to 28 points; and fatigue subscale, 13 items with score from 0 to 52. Each item has five *likert*-type options graduated from 0 to 4: "Not at all", "A little bit"; "Somewhat"; "Quite a bit"; "Very much". The final score of *FACT-F*

is obtained by adding the scores of the five domains, and may vary from 0 to 160 points. The higher the number of points, the better the quality of life and the less the fatigue of the patients is. To obtain the score, the negative questions are reverted; then the answers of the domains are added up, and a proportional average is carried out in case of non answered items. It is acceptable a 50% score of non-answered questions. But 80% of answered questions are considered adequate.¹⁶ The instrument make questions about health condition in the last seven days, and was written for a reading level of a fourth grader of elementary level (9 - 10 years of age), and it can be self administrated applied in the form of an interview, read by the researcher to the participants, and applied by telephone.^{16,18}

Eastern Cooperative Oncology Group (ECOG)

Performance Status (PS)²⁵

For clinical evaluation of patients, we used the PS, a method of clinical evaluation of patients, recognized by the World Health Organization and widely used in patients with cancer. The scores vary from 0 to 4: PS 0 - normal activity; PS1 - symptoms of the disease, but ambulatory and with a normal daily routine; PS2 - out of bed more than 50 % of the time; PS3 - more than 50% of the time in bed, needing more intensive care; PS4 - restricted to bed.

Additional information

We also evaluated patient gender, marital status, and educational level, as well as the topography of the primary cancer, its stage and treatment. Demographic information on disease and treatment were obtained and collected from the medical register of patients.

Statistical analysis

Information obtained from the filled questionnaires was stored in an electronic environment, using Microsoft Excel and subsequently exported to the program *Statistical Package for the Social Sciences* (SPSS), version 13.0, for data consistency analysis and statistical treatment. Descriptive statistic (percentages or averages accompanied by the respective standards deviations) was calculated to describe

the characteristics of the subjects and the scores of each domain of the *FACT-F*. The qui-square test was used for the analysis of the categorical variables. The reproducibility of the questionnaire was tested through two evaluations: one in the moment of the inclusion in the study and on second repeated after a period from 3 to 14 days (average 6.5 days \pm 2.84), with the purpose to compare the results obtained by the same examiner in different times.

The reproducibility of information of the questionnaires was analyzed in the present study using two statistical procedures: intraclass correlation coefficient (ICC) for values obtained in two measurements (test-retest) and the scatter plot proposed by Bland-Altman, which compares graphically differences between values obtained in the test and the retest of *FACT-F* ($FACTF_{test} - FACTF_{retest}$) with the averages of two evaluations $[(FACTF_{teste} + FACTF_{reteste})]/2$. We considered as limit of agreement in Bland-Altman scatter plot twice the standard deviation of the average of the differences between the obtained results.^{26,27} Besides, we calculated Pearson correlation coefficient, aiming to compare results obtained with those of the original article of validation of *FACT-F* for the English language. Pearson correlation coefficient were classified in the following way: 0-0.25 - not correlated; 0.25-0.50 - weak correlation; 0.50-0.75 - moderated to good correlation; >0.75 very good to excellent correlation.²⁸ ICC can vary from 0 to +1, in this case indicating a high reproducibility, while ICC=0 indicates no reproducibility.²⁹ We used the significance level of $\alpha \leq 0.05$. We also calculated the confidence interval of 95 % (CI95%) for each ICC value.

Results

Sociodemographic and disease characteristics

Subjects of the study were 85 patients with an average age of 51.0 years (\pm 12.2), varying from 19 to 82 years of age; 65.9% (n=56) were female and 34.1% (n=29) male; the marital status of this population was: 23.5% unmarried, 42.4% married, 17.6 % separated/divorced and 16.5% widowers. Educational level was: 48.2% - elementary school; 35.3% -secondary school; 16.5% - college. As for the type of cancer, the most frequent were breast cancer (31.8%), colorectal cancer (21.4%), lymphoma (16.5%), lung (8.2 %), and other

types (22.1%): stomach, myeloma, Ewing/PNET, soft tissue sarcoma, osteosarcoma, melanoma, bladder and tymoma. Most cases were stage IV (38.8%) followed by stage III (35.3%), stage II (24.7%) and stage I (1.2%), all being treated with chemotherapy; from these, 57.6% were submitted to surgery and 34.1% received radiotherapy. *Performance Status (PS)* of subjects was: PS0 35.3%, PS1 51.8%, PS2 11.8%, PS3 1.2% and PS4 0%.

Administration of FACT-F

Regarding the way of applying the instrument, 36.5% self administered and 63.5% were interviewed by a researcher. Self-application were carried out by patients younger than those interviewed (age average 47.42 versus 52.81; $p = 0,048$). Figure 1 compares the distribution of educational level and *performance status* according to the application of the questionnaire. Interviewed patients had less schooling (elementary and secondary school) ($p < 0,001$). On the other hand, there was no statistically significant difference in *performance status* between the two different ways of applying the questionnaire ($p = 0,24$).

Reproducibility

Table 1 shows the average, intraclass correlation coefficients and Pearson correlation of scores obtained in the different domains regarding the test and the retest. No significant differences were observed on averages between the domains for the first and the second interviews. Values found for ICC for the domains varied between 0.72 for physical well-being and 0.91 for social/family well-being; fatigue subscale reached 0.88 and FACT-F as a whole, 0.91. Pearson correlation coefficient was excellent ($r >$

0.75) for all domains, except for well-being physical, that presented a moderated correlation ($r = 0.58$). The highest correlation found referred to social/family well-being ($r = 0.84$). The correlation coefficient was excellent for *FACT-F* ($r = 0.85$). These high correlation coefficients indicate a high degree of stability in time, showing that there were no significant changes in measures of quality of life and fatigue.

Intraclass correlation did not vary regarding educational level for the physical well-being domain (elementary school: ICC=0.79, CI 95% = 0.61-0.89; secondary: ICC=0.64. CI 95% = 0.25-0.82; college: ICC=0.58. CI 95% = -0.35-0.87); social/family well-being (elementary school: ICC=0.96. CI 95% = 0.94-0.98; secondary school: ICC=0.81. CI 95% = 0.59-0.91; college: ICC=0.57. CI 95% = -0.27-0.86); emotional well-being (elementary school: ICC=0.94. CI 95% = 0.89-0.97; secondary school: ICC=0.86. CI 95% = 0.71-0.93; college: ICC=0.75. CI 95% = 0.24-0.92); functional well-being (elementary school: ICC=0.89. CI 95% = 0.81-0.94; secondary school: ICC=0.76. CI 95% = 0.49-0.89; college: ICC=0.79. CI 95% = 0.36-0.93); subscale fatigue (elementary school: ICC=0.93. CI 95% = 0.87-0.96; secondary school: ICC=0.79, CI 95% = 0.57-0.90; college: ICC=0.65. CI 95% = -0.12-0.893) and for FACT-F (elementary school: ICC=0.94. CI 95% = 0.88-0.97; elementary school: ICC=0.80, CI 95% = 0.57-0.91; college: ICC=0.79, CI 95% = 0.40-0.93).

As for the way of applying the questionnaire, there was no intraclass correlation difference between domains: physical well-being (interviewed: ICC=0.83, CI 95% = 0.49-0.83; self-applied: ICC=0.69, CI 95% = 0.36-0.85); social/family well-being (interviewed: ICC=0.92, CI 95% = 0.87-0.96; self-applied: ICC=0.88, CI 95% = 0.62-0.95); emotional well-being (interviewed: ICC=0.89, CI 95% = 0.81-0.93; self-applied: ICC=0.93,

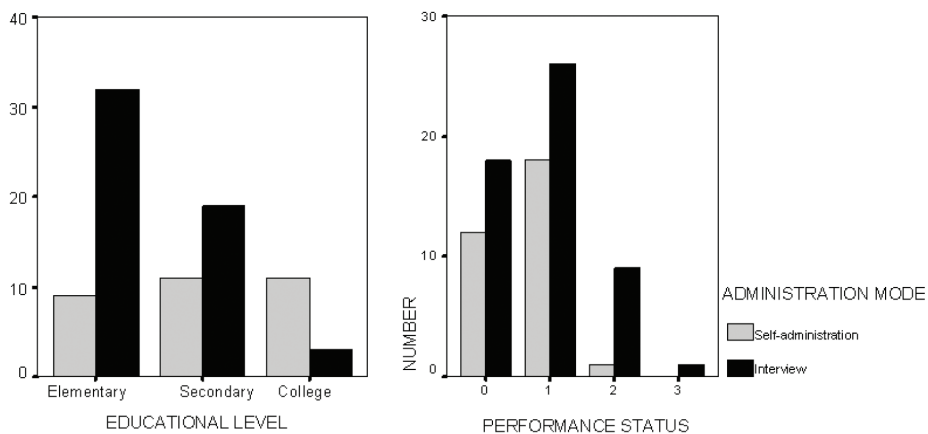


Figure 1 - Educational level and performance status of patients according FACT-F administration mode

Table 1 - Average, intraclass correlation coefficient and Pearson correlation coefficients of scores of the different domains in test and retest (n=85)

Domains (scores variation)	Average (\pm SD)		Intraclass correlation (CI95%)	Pearson Correlation
	Test	Retest		
Physical Well-Being (0-28)	22.70 (\pm 3.93)	21.69 (\pm 4.54)	0.72* (0.58-0.82)	0.58*
Social/Family Well-Being (0-28)	21.71 (\pm 4.12)	21,00 (\pm 4.33)	0,91* (0,86-0.94)	0.84*
Emotional Well-Being (0-24)	20.00 (\pm 4.42)	19.88 (\pm 4.09)	0.90* (0.86-0.94)	0.83*
Functional Well-Being (0-28)	18.94 (\pm 5.17)	17.99 (\pm 5.36)	0.86* (0.79-0.91)	0.76*
Subscale Fatigue (0-52)	41.43 (\pm 7.79)	41.26 (\pm 9.18)	0.88* (0.81-0.92)	0.79*
FACT-F (0-160)	124.79 (\pm 19.20)	121.01 (\pm 22.10)	0.91* (0.86-0.94)	0.85*

FACT-F: Functional Assessment of Cancer Therapy Fatigue; SD: standard deviation; CI: confidence interval. **p* value <0.0001.

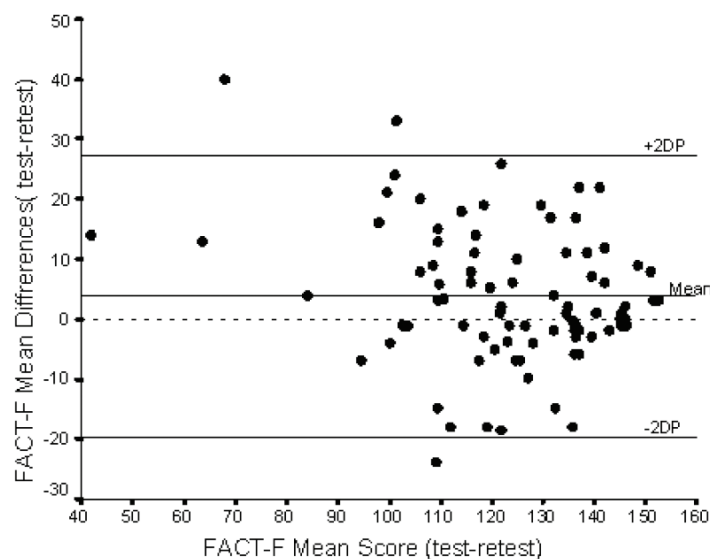
CI 95% = 0.85-0.96); functional well-being (interviewed: ICC=0.87, CI 95% = 0.78-0.93; self-applied: ICC=0.83, CI 95% = 0.59-0.92); fatigue subscale (interviewed: ICC=0.91, CI 95% = 0.84-0.95; self-applied: ICC=0.82, CI 95% = 0.63-0.91) nor for FACT-F (interviewed: ICC=0.93, CI 95% = 0.88-0.96; self-applied: ICC=0.87, CI 95% = 0.61-0.94).

Figure 2 presents Bland-Altman dispersal diagram showing the average values of FACT-F scores (abscissa) and the individual differences between values obtained in the test and in the retest (ordinate). The average of differences found was 3.78 (standard deviation= 11.70) and the limits (average \pm 2 standard deviations) were

+27.18 and -19.62. Most points are contained on the established limits. An analysis of the difference between the averages of test and retest reveals the distribution of the points to be concentrated near to average value of the differences, and only two cases were higher than the superior limit and one less than the inferior limit, thus confirming the good agreement between test and retest.

Discussion

Several instruments for evaluating quality of life in patients with cancer are being developed in Europe

**Figure 2** - Bland-Altman scatter plot for agreement between the test and retest of the application of FACT-F questionnaire for the evaluation of fatigue and quality of life in patients with cancer

and the United States mainly in the English language.^{30,31} Using such an instrument in Brazil requires a trans-cultural adaptation by using psychometric measures.^{32,33} One of the stages for validating a questionnaire is the test - retest of the version translated to Portuguese. In this study the instrument *FACT-F* was applied to 85 patients with different types of cancer. The participants of this research had mainly cancer in stages III and IV, the profile of the population treated in INCA, where more than 50% of the patients present advanced disease at diagnostic.³⁴

Sixty three per cent of the individuals had chosen the interview; in it the questionnaire was read and filled out by the interviewer, instead of self administered it. This can be due to the low educational levels and to the fact that most patients are aged. The same happened in the study for validation of *FACT-G* in Spanish for patients with cancer in Uruguay.³⁵

We noticed no significant differences between the averages of the scores of four analyzed domains of *FACT-G* and the fatigue subscale. Intraclass correlation did not differ regarding educational levels and way of application.

Intraclass correlation coefficient was high for all domains, and the highest intraclass correlation was obtained for the social/family well-being domain (ICC=0.91) and the *FACT-F* questionnaire that obtained an excellent ICC (ICC=0.91). The lowest correlation was observed in the physical well-being domain (ICC=0.72). As in the study of Yellen et al.¹⁵ intraclass correlation was not calculated, a comparison is not possible with the present study. We also observed that Bland-Altman scatter plot showed a small difference between the scores of the test and the retest, because most points were inside the established limits.

Pearson correlation coefficients values found in the present study for *FACT-F* ($r=0.85$) and the subscale fatigue ($r=0.79$) are lightly inferior to the values of Pearson correlation coefficients observed for *FACT-F* ($r=0.87$) and the subscale fatigue ($r=0.90$) in the validation study of the original *FACT-F* English version questionnaire, published by Yellen et al.,¹⁵ which applied it to 50 subjects from 19 to 83 years of age, with test - retest in an interval from 3 to 7 days. In the present study it was not possible to determine if this difference was due to instability of the clinical condition of patients, since some retests were carried out up to 14 days after test, when their condition might be equal, worse or better than in the day of test.

Although in the present study we used Pearson correlation coefficient, mainly for comparing results obtained to those of already published studies, it is known

that it has limitations as a tool for evaluating agreement, for it evaluates only linear relations between the variables and do not account for a systematic bias^{26,27}, something that makes ICC preferable for evaluate reproducibility.

Besides, since in the second application the patient already knows the instrument, reproducibility may be overestimated; conversely, the variations in the health condition and in learning may underestimate it. In spite of these limits, the analysis of reproducibility is important for the evaluation of the instrument's stability.²²

Conclusion

This study demonstrated that the *FACT-F* instrument has a good reproducibility test - retest in heterogeneous series of patients, with different types of cancer, *performance status* and staging, what allows it to be applied in Brazilian studies on quality of life and fatigue in patients with cancer, making possible to compare the results of evaluations and interventions with other studies carried out in the country.

Conflicts of Interest: None

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Collaborators

N M Ishikawa contributed in the preparation of the manuscript of the study, data collection, editorial assistance, statistic analysis, discussion of results and final approval of the text. L C S Thuler contributed to the review of the content of the paper, statistic analysis, discussion of results and final approval of the text. AG Giglio contributed for the choice of patients, data collection and has also taken part in the final approval of the text. C S R Baldotto contributed for the choice of patients, data collection and has also taken part in the final approval of the text. C J C Andrade contributed for the choice patients, data collection and has also taken

part in the final approval of the text. S F M Derchain was responsible for conceiving and designing the study, has taken part of the review of the content of the paper and the final approval of the text.

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