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Letter to the editor

Edmonton Functional Assessment Tool – revised version (EFAT-2): Translation into Italian and assessment of its psychometric properties

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Dear Editor—The revised version of the Edmonton Functional Assessment Tool (EFAT-2) was developed to evaluate functional status and to monitor the effectiveness of rehabilitation treatments in people with advanced cancer [1] for whom it has showed good psychometric properties [2–4].

The EFAT-2 is an 11-item measurement tool. The first 10 items evaluate the state of single functions such as communication, mental status, motivation, pain, dyspnea, fatigue, balance, mobility, locomotion, and activities of daily living. The last item summarizes the overall functional status of the person. The total score ranges from 0 (best score) to 30 (worst score) [1].

To date, no Italian version of the EFAT-2 exists. This letter describes the translation and cross-cultural adaptation of the EFAT-2 into Italian, and highlights its psychometric properties in people with advanced cancer admitted to 2 palliative care centers. The protocol was approved by the institutional review board of the University of L'Aquila (approval no. 52/202.021).

Following the guidelines of Guillemin et al. [5], and Beaton et al. [6], the EFAT-2 [1] was independently translated into Italian by 2 non-medical professional translators and 1 physician, whose native language was Italian. After the 3 translated versions were completed, a meeting was held to produce a consensus Italian version (Version 1). This consensus version was translated back into English by 2 other non-medical professional translators whose native language was English. A harmonization meeting was held with all translators and the healthcare committee, and we obtained a new, consensus Italian version (Version 2) that was semantically and grammatically equivalent to the original version (EFAT-2-IT, see Appendix). Subsequently, we began a pilot test involving 10 people with advanced cancer (mean [SD] age: 65 [36] years; 5 women) to determine whether the questions of the EFAT-2-IT were understandable.

To evaluate the psychometric properties (reliability, validity and responsiveness) of the EFAT-2-IT, we recruited a convenience sample of people with advanced cancer admitted to 2 palliative care centers between January 2013 and January 2021. This long recruitment period was necessary to acquire an adequate number of participants, at least 50 according to Altman [7]. Participants were included if they were (1) ≥18 years old, (2) admitted to a palliative care center, and (3) clinically able to sustain rehabilitation treatment. They were excluded if they had conditions other than cancer or had cognitive deficiencies. Participants had to provide written consent.

For the baseline assessment, participants were interviewed in their own, comfortable room. Two independent assessors (rater 1 and rater 2) administered the EFAT-2-IT questions and rated their answers to examine inter-rater reproducibility. At the same time, the Italian versions of the Eastern Cooperative Oncology Group Performance Status (ECOGPS-IT) [8], and Barthel Index (BI-IT) [9] questionnaires were also administered. Two days later, the EFAT-2-IT was re-administered by rater 1 to examine test-retest reproducibility. This short interval was selected to minimize time-dependent clinical changes. Participants then underwent rehabilitation treatment (mean duration: 15 days; range 10–45 days), which included respiratory exercises, mobility training, transfer education, balance training, lymphedema therapy, strength exercises, pain relief treatments, and education. At the end of the rehabilitation treatment, the EFAT-2-IT was re-administered to participants. At the same time, the 2 raters independently completed a 7-point global rating of change (GROC) form (which ranged from "very much worse" to "very much improved") to answer the follow question: "How is the person today, in comparison to his/her first visit?" The raters' GROC scores were then averaged to give an overall GROC score; this was used as our external criterion for the evaluation of responsiveness [10].

Cronbach's alpha, intraclass correlation coefficients ($ICC_{2,1}$ and $ICC_{2,k}$) based on a 2-way ANOVA, and Spearman rank correlation coefficients (rho), all with 95% confidence intervals (95% CI), were used to evaluate internal consistence, test-retest and inter-rater reproducibility, and construct validity, respectively. Additionally,

Abbreviations: AUC, Area under the curve; BI, Barthel Index; CFI, Comparative Fit Index; CI, Confidence interval; CFA, Confirmatory Factor Analysis; ECOGPS, Eastern Cooperative Oncology Group Performance Status; EFAT-2, Edmonton Functional Assessment Tool - revised version; ES, Effect size; GROC, Global Rating of Change; ICC, Intraclass correlation coefficients; MCID, Minimal clinically important difference; MDC_{95}, Minimal detectable change based on 95% CI; ROC curve, Receiver operating characteristic curve; RMSEA, Root mean square error of approximation; SEM, Standard error of measurement; SRM, Standardized response mean; TLI, Tucker-Lewis Index

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standard error of measurement [SEM = SD × $\sqrt{(1-ICC_{2,1})}$] and minimal detectable change based on 95% CI (MDC_{95} = 1.96 × $\sqrt{2}$ × SEM) were calculated.

To determine structural validity, we conducted a confirmatory factor analysis (CFA) for EFAT-2-IT baseline responses using the predetermined domains (physical ability, cognitive/affective, and pain) of EFAT-2 [1]. We hypothesized that using these 3 pre-determined domains, with each item loaded onto 1 domain, would have goodness-of-fit indices within acceptable limits (Comparative Fit Index [CFI] and Tucker-Lewis-Index [TLI]) >0.90 and Root Mean Square Error of Approximation [RMSEA] >0.08) [11]. Construct validity was tested by determining the relationship between the EFAT-2-IT scores and the ECOGPS-IT scores, and BI-IT scores. Cronbach's alpha >0.70 was considered acceptable [12]. The ICC score was interpreted as follows: ≥0.75 = excellent; 0.74 to 0.40 = moderate-to-good; and <0.40 = poor [13]. The rho values were interpreted as follows: 0.00 to 0.19 = absent; 0.20 to 0.29 = weak; 0.30 to 0.39 = moderate; 0.40 to 0.69 = strong; and ≥0.70 = very strong [14]. Responsiveness, the ability of the outcome measure to monitor changes over time (e.g., after rehabilitation treatment), was evaluated using 2 distribution-based methods (the effect size [ES] [15] and the standardized response mean [SRM]) [16], and an anchor-based method, the receiver-operating characteristic (ROC) curve [10]. The ES was calculated as the mean difference between the baseline and post-treatment scores (i.e., mean change in score) divided by the baseline standard deviation (SD). The SRM was calculated as the mean change in score divided by the SD of the change in score. The ES and SRM scores were interpreted as follows: 0.2 = small; 0.3 to 0.7 = moderate; and ≥0.8 = large [17]. The ROC curve was based on the changes, after rehabilitation treatment, in the EFAT-2-IT score and GROC score. In plotting the ROC curve, the GROC score was dichotomized to identify participants who experienced a clinically meaningful reduction in symptoms [10]. We chose a GROC ≥5 to represent an important change, and scores ≤4 to represent no change. The point of the ROC curve on the upper-most left-hand corner was identified as the optimal cut-off change score and was used to estimate the minimal clinically-important difference (MCID), defined as the magnitude of change that best distinguishes between participants with improved conditions, and those whose condition was unchanged [17]. We also computed the area under the ROC curve (AUC), which can be interpreted as the probability of correctly identifying a participant with an improved condition from randomly selected pairs of participants who may or may not have an improved condition [18]. The AUC was interpreted as follows: ≥0.90 = excellent; 0.89 to 0.70 = adequate; and <0.70 = poor [18]. Moreover, floor and ceiling effects were investigated and considered present if more than 15% of participants achieved the lowest (0) or highest (30) possible score [19].

All the analyses were conducted with MedCalc (version 14.8.1 for Windows). Parametric or non-parametric tests were used for statistical analysis, according to the normality of distribution of data as verified by the Shapiro-Wilk test. The level of statistical significance was set at $p \leq 0.05$.

In total, 64 participants were enrolled in this study; their characteristics are shown in Table 1. After the rehabilitation treatment, the overall GROC scores indicated that the condition of 22 (34%) participants had improved, that 14 (22%) remained stable that and for 28 (44%), their condition had worsened.

Results of EFAT-2-IT psychometric properties, which are summarized in Table 2, showed (1) an acceptable internal consistency (Cronbach's alpha 0.76). When the alpha coefficient was calculated for the overall scale, by eliminating each of the 10 items one at a time, not only was the range 0.69 to 0.79, but also no single item substantially changed the internal consistency. The results also showed (2) excellent test-retest reproducibility ($ICC_{2,1}$ 0.96, 95% CI 0.93; 0.98) with a SEM of 0.9 and an MDC_{95} of 2.5; (3) very good inter-rater agreement ($ICC_{2,k}$ 0.98, 95% CI 0.96; 0.98); (4) stronger correlation of the EFAT-2-IT score with the ECOGPS-IT (rho = 0.77) than with the BI-IT score (rho = –0.46); and (5) that the EFAT-2-IT was responsive to changes in participant condition with an ES of –0.68, an SRM of –0.67, and an MCID >4 (sensitivity: 80, specificity: 85.7) (Fig. 1), with an AUC of 0.76. From the CFA, the 3-factor model based on the existing factor structure physical ability, cognitive/affective, and pain) was a good fit with the CFI (0.973), TLI (0.969) and RMSEA (0.082).

Table 1
Baseline characteristics of 64 people with advanced cancer in 2 palliative care centers who participated in the evaluation of an Italian version of the Edmonton Functional Assessment Tool - revised version (EFAT-2).

Characteristics	
Participants, n	64
Women/Men, n	36/28
Age in years, mean (SD)	68.7 (19)
Primary cancer diagnosis, n (%)	
Lung	13 (20%)
Gastrointestinal	11 (17%)
Breast	10 (16%)
Prostate	8 (13%)
Gynecological	6 (9%)
Brain	6 (9%)
Urological	5 (8%)
Lymphoma	2 (3%)
Head and neck	1 (2%)
Other/unknown	2 (3%)
Time in months since cancer onset, mean (SD)	53 (18)
Metastasis, n	39
Previous treatment, n	
Chemotherapy	58
Radiotherapy	8
Surgery	23
EFAT-2-IT score (range 0–30), mean (SD)	15.8 (4)
BI-IT score (range 0–100), mean (SD)	30.5 (14)
ECOGPS-IT score (range 0–5), mean (SD)	2.3 (1)

BI-IT, Italian version Barthel Index (a higher score indicates a better condition); ECOGPS-IT, Italian version of Eastern Cooperative Oncology Group Performance Status (a higher score indicates a worse condition); and EFAT-2-IT, Italian version of the Edmonton Functional Assessment Tool - revised version (a higher score indicates a worse condition).

We encountered no difficulties in translating the EFAT-2. The back translation corresponded accurately to the original English and any minor linguistic discrepancies were easily resolved in a healthcare committee meeting. The 3-factor model of the original version of the EFAT-2 questionnaire was confirmed by the CFA. The MDC_{95} and MCID of the EFAT-2-IT questionnaire were 2.5 and 4, respectively. Cronbach's alpha, although lower than that of the originally revised version [1], indicated a good internal consistency. Our results showed a high score both for test-retest and inter-rater reproducibility. However, because test-retest reliability was not assessed in previous studies, direct comparison with our results was not possible. As for inter-rater reproducibility, our ICC value was like that reported by Kaasa et al. [1] for the original version of the EFAT-2, and higher than that reported by Gardiner and Samuel [4].

When compared with the first EFAT version [2], the EFAT-2-IT score showed a weaker correlation with the ECOGPS-IT score. Likewise, the EFAT-2-IT score was more weakly correlated with the BI when compared to results reported by Gardiner and Samuel [4].

Gardiner and Samuel [4] were the first to determine the responsiveness of the EFAT-2, but they used only a distribution-based method (i.e., the ES) for this purpose. To our knowledge, this is the first study to use all recommended statistical methods, including the distribution-based methods (ES and SRM) and the anchor-based method (ROC curve) to determine the responsiveness of the EFAT-2. The EFAT-2-IT was clearly more responsive than the ECOGPS-IT and BI-IT in our study population. Our ES value was slightly higher than that reported by Gardiner and Samuel [4]. Because no other studies

Table 2
Results of all recommended statistical methods required to determine the reliability and responsiveness of an Italian version of the Edmonton Functional Assessment Tool - revised version psychometric properties as evaluated in a group of 64 people with advanced cancer in 2 palliative care centers.

Properties	Values (95% CI)	Classification
Reliability (internal consistency)		
Chronbach's alpha, variation with exclusion item-to-item	0.76 (0.62; 0.89)	Acceptable
Reliability (reproducibility)		
Test-retest $ICC_{2,k}$	0.96 (0.93; 0.98)	Excellent
Inter-rater $ICC_{2,1}$	0.98 (0.96; 0.98)	Excellent
Construct validity		
Correlation with the ECOGPS-IT (rho)	0.77 (0.62; 0.87)	Very strong correlation
Correlation with the BI-IT (rho)	−0.46 (−0.66; −0.18)	Strong negative correlation
Responsiveness		
ES	−0.68	Moderate
SRM	0.67	Moderate
ROC curve, (area under the curve)		
MCID, points	0.76 (0.56; 0.90)	
≥ 4	Acceptable discrimination	
MDC	≥ 2.5	

BI-IT, Italian version of the Barthel Index; CI, Confidence interval; ECOGPS-IT, Italian version of the Eastern Cooperative Oncology Group Performance Status; EFAT-2-IT, Italian version of the Edmonton Functional Assessment Tool - revised version; ES, Effect size; ICC, Intraclass correlation coefficient; MCID, Minimal clinically important difference; MDC, Minimal detectable change; rho, Pearson's Correlation; ROC, Receiver operating characteristic; SRM, Standardized response mean.

have assessed the responsiveness of EFAT-2 with the ROC curve analysis, our data cannot be directly compared.

A methodological limitation of our study is the small sample size. Nevertheless, we consider it representative of people with advanced cancer who have been routinely referred to a palliative care center. Our study exclusively recruited people with advanced cancer in a palliative care setting, so we have confidence that the psychometric data would be the same for other people with advanced cancer.

Two other strengths of this study include the use of standardized methods for all assessment procedures and the novel use of all recommended statistical methods to determine reliability and responsiveness of the Italian test version.

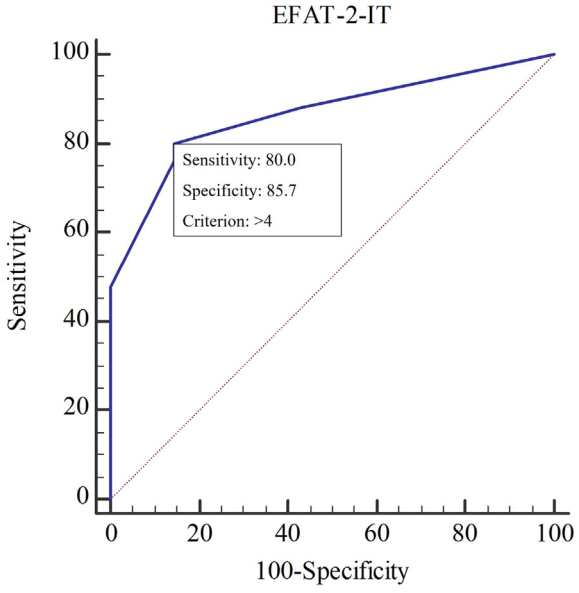

Fig. 1. The receiver operating characteristic (ROC) curve of the Edmonton Functional Assessment Tool in Italian (EFAT-2-IT).

In conclusion, the EFAT-2-IT is a reliable, valid, and responsive functional performance assessment tool for people with advanced cancer in a palliative care center and undergoing a rehabilitation program. We therefore recommend the use of the EFAT-2 as a standard outcome measure for Italian-speaking people with advanced cancer who undergo rehabilitation treatments in palliative care centers.

Data availability

Data will be made available on request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data are available upon reasonable request.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.rehab.2023.101733.

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