

Validation of the Bulgarian versions of the EORTC QLQ-C30 and FACT-G: reliability, construct validity, and agreement in cancer survivors

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Abstract

Health-related quality of life (HRQoL) is a critical outcome measure in oncology research and clinical care. This study aimed to translate, culturally adapt, and psychometrically validate the Bulgarian versions of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30 (EORTC QLQ-C30) and the Functional Assessment of Cancer Therapy–General (FACT-G), focusing on Internal Consistency (IC), Test–Retest Reliability (TRR), and Construct Validity (CV) in Cancer Survivors (CS) diagnosed with breast, lung, or colorectal cancer. A total of 235 Bulgarian CS (mean age 62.3 ± 11.2 years; 118 males, 117 females) were recruited from five tertiary care hospitals in a cross-sectional study design. The EORTC QLQ-C30 and FACT-G were translated and culturally adapted according to the official EORTC and FACIT guidelines. Psychometric evaluation included data quality (floor and ceiling effects, missing responses), IC, TRR, and CV assessed via convergent and Discriminant Validity (DV). A subsample of 78 study participants (33.2%) completed both questionnaires twice over a 14-day interval for TRR assessment. CV was supported by strong item-scale and cross-instrument correlations ($r = 0.62\text{--}0.81$). IC was excellent across all domains (Cronbach’s $\alpha = 0.88\text{--}0.95$), and TRR demonstrated high stability (ICC = $0.75\text{--}0.89$). Bland–Altman analysis showed acceptable agreement, with a mean difference of 23.20 (95% CI: 21.87–24.53) and limits of agreement ranging from +3.77 to +42.63. Minimal Floor Effects (FE) were observed, while Ceiling Effects (CE) were noted in specific domains (e.g., Social Functioning (SF) and Global Health (GH) in the EORTC QLQ-C30; Social Well-Being (SWB) and Emotional Well-Being (EWB) in the FACT-G). The findings support that the Bulgarian versions of the EORTC QLQ-C30 and FACT-G are valid, reliable, and culturally appropriate instruments for evaluating HRQoL in Bulgarian CS. Their use is recommended in both clinical practice and research contexts.

Key Words: EORTC QLQ-C30; FACT-G; health-related quality of life; psychometric validation; Bulgaria.

The global population of Cancer Survivors (CS) continues to grow due to advances in diagnosis, surgical techniques, chemotherapy, and radiotherapy. Cancer remains a major public health challenge across EU member states, with Lung Cancer (LC) being the most commonly diagnosed cancer type in Europe, representing 12.2% of all new cancer diagnoses and approximately 20% of cancer-related deaths, followed by Colorectal Cancer (CC) (9.4%), and Breast Cancer (BC) (6.9%).¹

Among European Union (EU) countries, the highest LC mortality rates in 2021 were reported in Denmark and the Netherlands (both 6.0%), followed by Ireland (5.5%). In contrast, Bulgaria reported comparatively lower proportions of cancer-related deaths due to LC (2.2%), as well as some of the lowest mortality rates for CC and BC, with rates of 1.8% for each.²

Both, LC and CC remain the most frequently diagnosed malignancies among Bulgarian men, with higher incidence rates compared to their counterparts in other EU countries. Approximately 5,600 new cases of LC and 4,000 new cases of CC are diagnosed in Bulgaria annually. LC is also the leading cause of cancer-related mortality among men, accounting for around 4,700 deaths annually, while CC contributes to over 2,000 cancer-related deaths per year. BC is the most common malignancy among Bulgarian women, with an estimated 4,100 new cases and approximately 1,400 deaths recorded annually.³

CSs represent a highly diverse population, with variations in age, sex, race and ethnicity, socio-economic, and employment status. In addition, CSs exhibit a broad spectrum of health- and cancer-related characteristics, including cancer type, age at diagnosis, weight status, and co-morbidities. This heterogeneity underscores the importance of personalized lifestyle interventions and systematic evaluation of treatment outcomes, particularly in terms of Health-Related Quality Of Life (HRQoL).^{4,5}

HRQoL is defined as the value assigned to the duration of life, modified by impairments, functional states, perceptions, and social opportunities influenced by disease, injury, treatment, or policy.⁶ HRQoL has emerged as a critical outcome measure in oncology research and practice, prompting the development of numerous cross-culturally validated instruments. Among the most widely used cancer-specific tools are the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30)⁷ and the Functional Assessment of Cancer Therapy—General (FACT-G).⁸

To our knowledge, no published studies have detailed the cross-cultural adaptation and psychometric validation of the EORTC QLQ-C30 and FACT-G questionnaires for use among Bulgarian CS.^{9,10} This gap is particularly relevant in light of the growing commitment among Bulgarian oncologists, Surgical Oncologists (SO), Physical and Rehabilitation Medicine (PRM) specialists, and other Healthcare Professionals (HCPs) to systematically evaluate treatment outcomes, rehabilitation strategies, and Patient-Reported Outcomes (PRO) such as HRQoL. The cross-cultural adaptation and validation of the Bulgarian versions of EORTC QLQ-C30 and FACT-G are essential to ensure accurate, re-

liable, and culturally appropriate tools for evaluating PRO in clinical practice and research.

Aim of the study

The aim of this study was to translate, culturally adapt, and psychometrically validate the Bulgarian versions of the EORTC QLQ-C30 and FACT-G questionnaires, focusing on Internal Consistency (IC), Test–Retest Reliability (TRR), and Construct Validity (CV) in CS diagnosed with breast, lung, or colorectal cancer.

Materials and Methods

Data collection and study participants

This cross-sectional validation study was conducted between November 2023 and May 2025 among adult CS receiving follow-up care at tertiary care hospitals in Pleven, Haskovo, Burgas, Plovdiv, and Ruse, Bulgaria. A total of 235 participants were recruited, with a mean age of 62.3 ± 11.2 years; the sample included 118 males (50.2%) and 117 females (49.8%). The cohort comprised 93 lung CS (39.5%), 77 colorectal CS (32.7%), and 65 breast CS (27.8%). Eligibility criteria included: i) age ≥ 18 years; ii) confirmed diagnosis of breast, lung, or colorectal cancer, regardless of disease stage or time since diagnosis; iii) receipt of any form of cancer treatment (e.g., surgery, chemotherapy, radiotherapy, or immunotherapy); iv) life expectancy greater than six months; and v) ability to read and understand Bulgarian. Exclusion criteria were: i) diagnosis of a severe psychiatric disorder (e.g., schizophrenia or active psychosis) or cognitive impairment that could interfere with questionnaire completion; ii) receipt of end-of-life or hospice care; and 3) insufficient proficiency in Bulgarian to independently complete study instruments. Breast, lung, and colorectal CS were selected due to their high prevalence and substantial contribution to the national cancer burden in Bulgaria,² thereby ensuring that the study population was representative and appropriate for the cross-cultural validation of Quality Of Life (QoL) measures.¹² A subsample of 78 study participants (33.2%) of the total 235 CS completed the EORTC QLQ-C30 and FACT-G questionnaires twice, with a 14-day interval to assess TRR. This time frame was chosen to minimize recall bias while ensuring that participants' Health Status (HS) was unlikely to have changed significantly. Both test and retest administrations were conducted using the same mode (paper-based, in-person), and consistent settings were used, including Surgery Departments, PRM Departments, and the Medical Diagnostic Consultative Center. CS of our study were instructed to complete the questionnaires independently without consulting other individuals, and were asked to reflect on their experiences over the previous seven days. The process was supervised by trained study administrators (H.B., J.P., D.S., Y.K.). All study participants signed written informed consent prior to enrollment, and all procedures were conducted in accordance with the Declaration of Helsinki (2013) and was approved by the Ethics Committee at the University Hospital «Sveta Marina», Pleven, Bulgaria, (Registry No. #223/13.10.2023).

Questionnaires

The EORTC QLQ-C30 is a widely used questionnaire for assessing HRQoL in cancer clinical trials.⁹ It consists of 30 items, which are scored and linearly transformed to yield values ranging from 0 to 100. These scores encompass five multi-item Functional Scales (FS), three multi-item symptom scales, six single-item symptom measures, and one global HS/QoL scale.^{7,12} Higher scores on the FS of the EORTC QLQ-C30 indicate better HRQoL, while higher scores on the symptom scales and individual items reflect a greater symptom burden. The EORTC QLQ-C30 has been psychometrically validated based on classical test theory, demonstrating satisfactory reliability and validity.¹³

The FACT-G is a validated cancer-specific instrument designed to measure general cancer HRQoL across four core domains, Social/Family Well-Being (SWB), Physical Well-Being (PWB), Functional Well-Being (FWB) and Emotional Well-Being (EWB). SWB refers to the entire family dynamics and functioning.⁸ The FACT-G questionnaire comprises 27 items, each scored on a 5-point Likert scale reflecting experiences over the past 7 days, and demonstrates robust psychometric properties.⁸ Higher scores on the FACT-G indicate better QoL, while lower scores reflect greater impairment.¹⁴

Translation and cross-cultural adaption of the EORTC QLQ-C30 and FACT-G

The translation and cross-cultural adaptation of the EORTC QLQ-C30 and FACT-G into Bulgarian were conducted in accordance with the standardized procedures outlined by the European Organisation for Research and Treatment of Cancer (EORTC)¹⁵ and the Functional Assessment of Chronic Illness Therapy (FACIT) system, respectively.¹⁶ Two native Bulgarian speakers (H.B., Y.K.) with advanced academic and clinical backgrounds independently produced forward translations of the original English-language instruments. For items presenting linguistic or conceptual challenges, multiple translation options (typically two or three alternatives) were proposed. The translation team conducted a consensus review to resolve discrepancies, ensuring semantic and cultural equivalence, as well as clinical appropriateness. Final item wording for the first Bulgarian version was determined by the translation coordinator, based on group consensus and alignment with the conceptual intent of the original items.

Backward translation and development of the second intermediate versions

The first intermediate Bulgarian versions of the EORTC QLQ-C30 and FACT-G were independently back-translated into English by two bilingual, bicultural native English speakers fluent in Bulgarian (J.P., D.S.). Neither had prior exposure to the original English versions of the instruments. Both translators were informed that the questionnaires were intended to assess HRQoL among Bulgarian CSs diagnosed with lung, colorectal, or breast cancer. Following the back-translation, the translation coordinator conducted structured review sessions with all translators to reconcile discrepan-

cies and ensure semantic, conceptual, and cultural equivalence. As part of the cultural adaptation process, minor modifications were implemented to enhance item clarity, cultural appropriateness, and respondent comprehension, while preserving the original conceptual meaning of each item.

Statistical analysis

The statistical analysis of the psychometric properties of the EORTC QLQ-C30 was conducted among Bulgarian CSs who had received various forms of cancer treatment (e.g., surgery, chemotherapy, or radiotherapy). Data were analysed by language version, Bulgarian and English. Analysis of data quality included distribution of scale scores (item means and standard deviations, floor and Ceiling Effects (CE), and missing item responses). To evaluate the presence of floor and CE, we calculated the proportion of respondents scoring the lowest (floor) and highest (ceiling) possible values on each EORTC QLQ-C30 and FACT-G domain.

Both, floor and CE were considered significant if more than 15% of respondents scored at the minimum or maximum scale range. IC reliability was assessed using Cronbach's α , with a value of ≥ 0.70 considered acceptable, and ≥ 0.90 considered ideal for clinical decision-making.¹⁷ TRR was assessed using the intraclass Correlation Coefficient (ICC), specifically the ICC (3,1) form based on a two-way mixed-effects model with absolute agreement. A threshold of ≥ 0.75 was interpreted as indicative of good temporal stability. CV was evaluated through both convergent and Discriminant Validity (DV), using Spearman's rank-order and Pearson correlation coefficients, depending on the level of measurement and distributional assumptions. Convergent Validity (CVg) was considered satisfactory when an item demonstrated a correlation of ≥ 0.40 with its hypothesized scale. DV was confirmed when each item correlated more strongly with its own scale than with other, unrelated scales.¹²

At the domain level, construct alignment between the EORTC QLQ-C30 and the FACT-G was assessed by computing Pearson correlation coefficients between conceptually related subscales. Correlations of $r \geq 0.60$ were considered evidence of moderate to strong agreement between instruments, supporting CVg.¹⁸ Bland-Altman analysis was applied to assess agreement between the EORTC QLQ-C30 and FACT-G instruments, with a mean difference (bias) and 95% limits of agreement calculated. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Armonk, NY, USA). A p-value < 0.05 was considered statistically significant for all tests.

Results

Descriptive statistics

Of the 290 initially enrolled CS, 235 completed the full study (81.1% retention), with 55 (18.9%) lost to follow-up. Finally, the total sample included 235 participants (mean age 62.3 ± 11.2 years), comprising 118 males

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(50.2%) and 117 females (49.8%). The most common cancer types were lung ($n = 93$; 39.6%), followed by colorectal ($n = 77$; 32.8%) and breast cancer ($n = 65$; 27.7%). A total of 195 participants (83.0%) completed the survey approximately one month after surgery and before the initiation of chemotherapy. Additionally, 162 participants (68.9%) completed the assessment following chemother-

apy, and 113 (48.1%) after radiation therapy. None of the participants had evidence of metastatic disease or comorbid conditions likely to significantly impair HRQoL. Patient sociodemographic and clinical characteristics are presented in Table 1.

Construct validity

CV of the instrument was supported through evidence of both convergent and DV, as assessed through item-scale and domain-level correlations. Following the EORTC QLQ-C30 guidelines,^{7,15} CVg is established when an item correlates moderately to strongly ($r \geq 0.40$) with its hypothesized scale. DV is confirmed when the correlation between an item and its intended scale is significantly greater than its correlation with other unrelated scales.¹⁷ In our study, Spearman's rank-order correlations were employed to examine both convergence and discrimination at the item level. At the domain level, Pearson correlations between the EORTC QLQ-C30 and a comparator instrument ranged from 0.62 to 0.81, indicating strong associations and consistent with findings from prior cross-cultural validation studies (Figure 1).¹⁹ The strongest correlations were observed for Physical Functioning (PF) ($r = 0.81$) and Role Functioning (RF) ($r = 0.79$). Moderate-to-strong correlations were also evident in Emotional Functioning (EF) ($r = 0.75$) and Cognitive Functioning (CF) ($r = 0.70$) (Table 2).²⁰ Table 3 summarizes the results of the Spearman correlation analysis between individual items and their respective scales on the EORTC QLQ-C30. All items demonstrated correlation coefficients equal to or greater than the minimum acceptable threshold ($\rho \geq 0.68$), with the majority surpassing the CVg criterion of $\rho \geq 0.70$ sup-

Table 1. Patient sociodemographic and clinical characteristics.

Sample Size (n)	n=235
Age (years, mean $\pm$ SD)	62.3 $\pm$ 11.2
Gender (%)	
Female (%)	n=117 (49.8)
Male (%)	n=118 (50.2)
Cancer type (%)	
Lung cancer (%)	n=93 (39.6)
Colorectal cancer (%)	n=77 (32.8)
Breast cancer (%)	n=65 (27.7)
Treatment received (%)	
Surgery	n=195 (83.0)
Chemotherapy	n=162 (68.9)
Radiation therapy	n=113 (48.1)

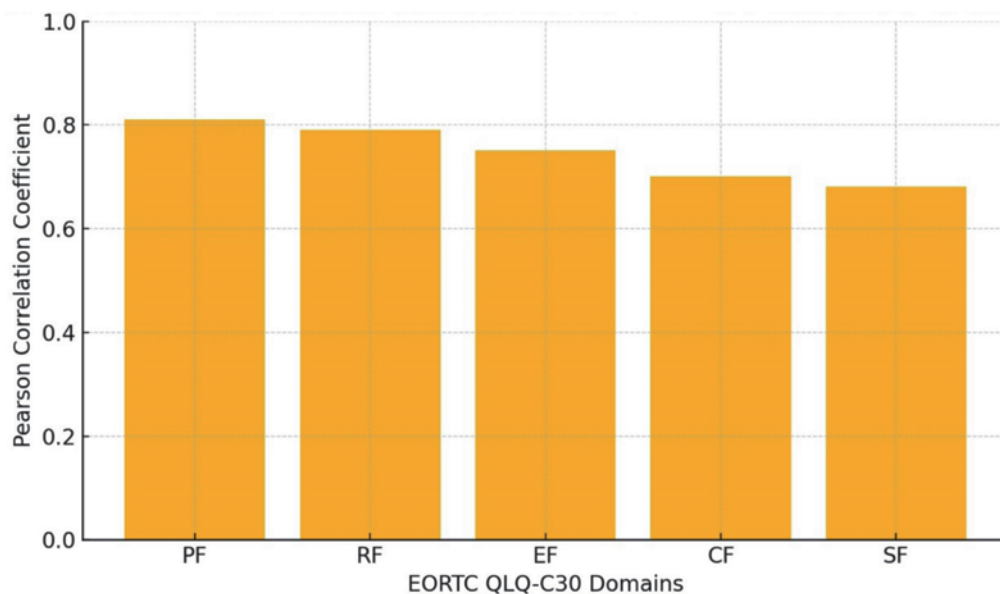


Figure 1. Pearson correlation coefficients between EORTC QLQ-C30 domains and the comparator instrument among Bulgarian cancer survivors.

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porting the CV of the instrument (Figure 2). Notably, the Global HS items (GH1 and GH2) showed particularly strong item-scale associations ($\rho = 0.79\text{--}0.81$), reflecting the stability and robustness of this domain across cultural contexts. Items within the Fatigue, Pain, and Nausea/Vomiting scales also exhibited strong internal alignment ($\rho \geq 0.70$), indicating sound scale-specific coherence even for symptom-based domains (Figure 3).

Floor and ceiling effects

For the EORTC QLQ-C30, CE were observed in the SF

domain, with 17.4% of participants reporting the maximum score. Similarly, CE we measured in the GH with 16.2% of CS of our study achieving the highest score, reflecting perceived stability or improvement in overall well-being post-treatment. No significant Floor Effects (FE) were observed across any EORTC domains, with all values falling below the 10% threshold.

Regarding the FACT-G questionnaire, CE were observed in the SWB (18.3%) and EWB (15.7%) domains, suggesting a potential clustering of positive responses in these domains. No domains showed evidence of notable FE.

Table 2. Pearson correlations between EORTC QLQ-C30 and FACT-G domains.

Domain	Pearson correlation (r)	Interpretation
PF	0.81	Strong correlation
RF	0.79	Strong correlation
EF	0.75	Moderate-to-strong correlation
CF	0.70	Moderate correlation

Correlations reflect the degree of association between conceptually aligned domains across the EORTC QLQ-C30 and FACT-G. All correlations were statistically significant at $p < 0.001$.

CF, cognitive functioning; EF, emotional functioning; PF, physical functioning; RF, role functioning.

Table 3. Spearman correlation of EORTC QLQ-C30 items with their own scales (Functional, Symptom, and Global QoL).

Item(s)	Corresponding scale	Spearman correlation (ρ)
PF1–PF5	Physical functioning	0.77–0.82
RF1–RF2	Role functioning	0.76–0.78
EF1–EF4	Emotional functioning	0.68–0.74
CF1–CF2	Cognitive functioning	0.69–0.71
FA1–FA3	Fatigue	0.73–0.75
PA1–PA2	Pain	0.76–0.78
NV1–NV2	Nausea/vomiting	0.70–0.72
GH1–GH2	Global health status/QoL	0.79–0.81

All item-scale correlations exceeded the recommended threshold for convergent validity ($\rho \geq 0.40$), with most items demonstrating moderate to strong correlations ($\rho \geq 0.70$), indicating high internal alignment and scale coherence. Item-to-own-scale correlations were higher than correlations with non-hypothesized scales, supporting DV.

CF, cognitive functioning; EF, emotional functioning; GH1–GH2, global health status/QoL; NV1–NV2, nausea/vomiting; PA1–PA2, pain; PF, physical functioning; RF, role functioning.

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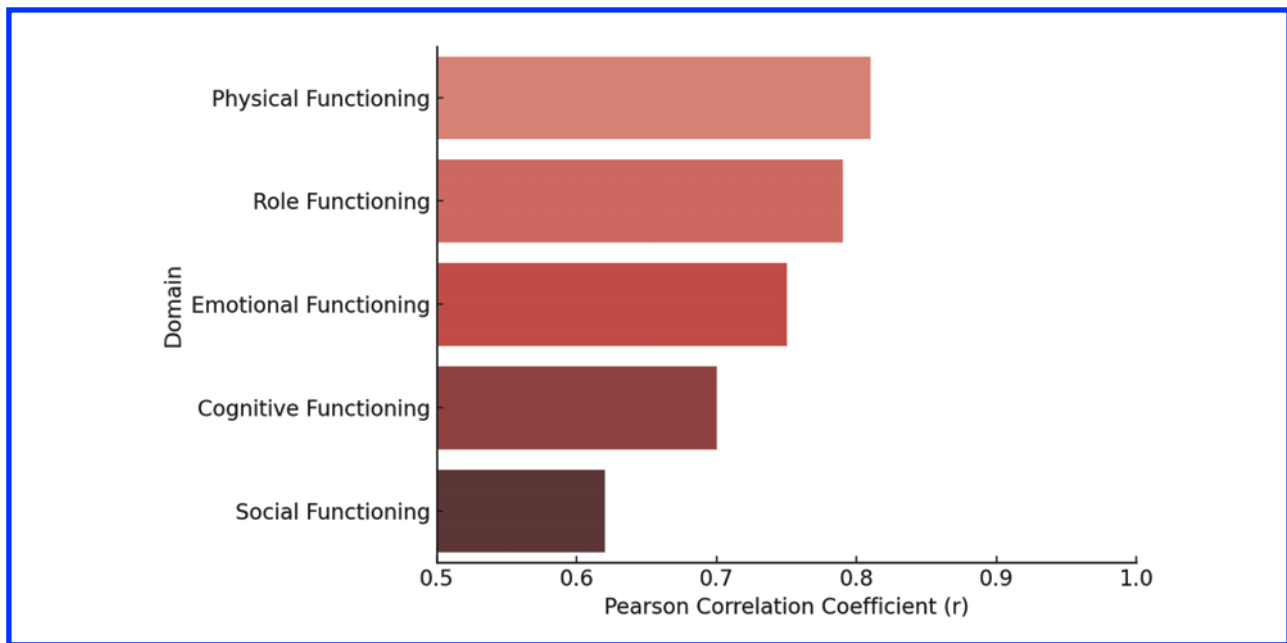


Figure 2. Pearson correlations between EORTC QLQ-C30 and FACT Domains.

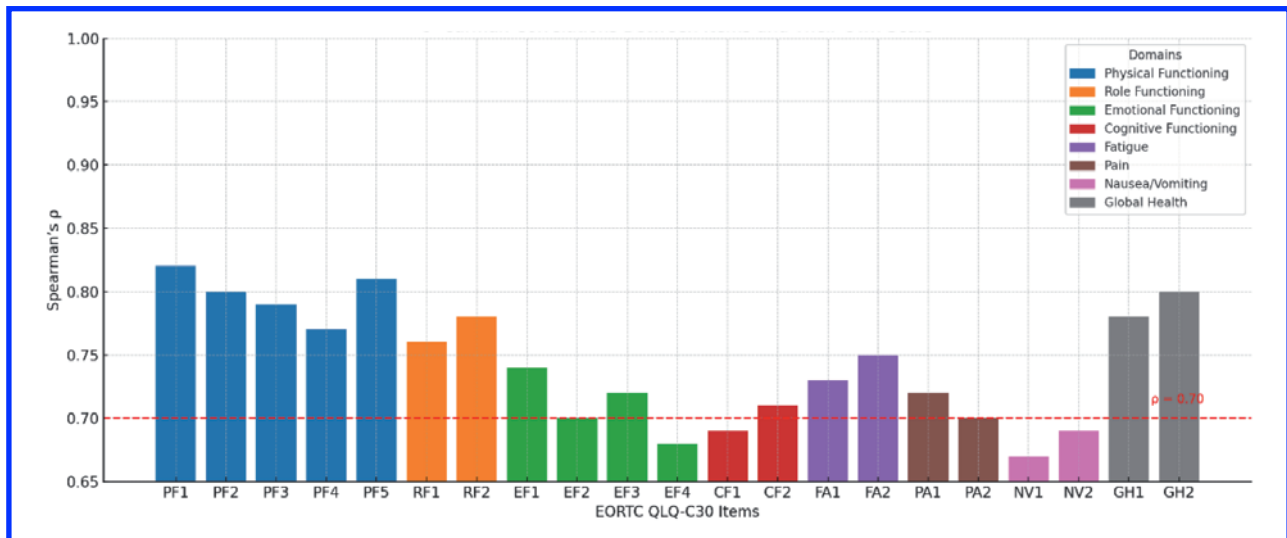


Figure 3. Spearman correlations of items with their own scale (EORTC QLQ-C30 extended).

Psychometric properties

Reliability

To evaluate the IC of the Bulgarian version of the EORTC QLQ-C30, we calculated Cronbach's α coefficients across its five core Functional Domains (FD).¹⁷ IC was assessed separately for both questionnaires, with thresholds of ≥ 0.70 for acceptability and ≥ 0.90 for clinical applications. As presented in Table 4, Cronbach's α values ranged from 0.92 to 0.95, demonstrating excellent IC across all subscales. Specifically, Cronbach's α values were 0.94 for PF,

0.92 for RF, 0.93 for EF, 0.95 for CF, and 0.92 for Social Functioning (SF). These values exceed the commonly accepted threshold of 0.70 and meet the stricter benchmark of 0.90 recommended for instruments used in individual-level clinical decision-making.¹⁸⁻²⁰ Similarly, the IC of the Bulgarian version of the α FACT-G, were evaluated across its four domains. Estimates were high, ranging from 0.88 to 0.91, indicating good to IC across all subscales (Table 5). Specifically, Cronbach's α was 0.91 for PWB, 0.88 for SWB, 0.89 for EWB, and 0.90 for FWB. These findings exceed the widely accepted cutoff of 0.70, and meet or ex-

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Table 4. Reliability of the EORTC QLQ-C30 domains in Bulgarian cancer survivors.

Domain	Cronbach's α	IC	ICC	TRR
PF	0.94	Excellent	0.88	Excellent
RF	0.92	Excellent	0.85	Excellent
EF	0.93	Excellent	0.86	Excellent
CF	0.95	Excellent	0.89	Excellent
SF	0.92	Excellent	0.75	Good

Cronbach's α values ≥ 0.90 indicate excellent internal consistency. ICC values ≥ 0.75 reflect good to excellent TRR. CF, cognitive functioning; EF, emotional functioning; IC, internal consistency; ICC, intraclass correlation coefficient; PF, physical functioning; RF, role functioning; SF, social functioning; TRR, test-retest reliability.

Table 5. Reliability of FACT-G domains in Bulgarian cancer survivors.

Domain	Cronbach's α	IC	ICC	TRR
PWB	0.91	Excellent	0.86	Excellent
SWB	0.88	Good	0.82	Good
EWB	0.89	Good	0.84	Good
FWB	0.90	Excellent	0.87	Excellent

Cronbach's α values ≥ 0.90 indicate excellent IC; values between 0.80–0.89 are considered good. ICC values ≥ 0.75 reflect good to excellent TRR. EWB, emotional well-being; FWB, functional well-being; IC, internal consistency; ICC, intraclass correlation coefficient; PWB, physical well-being; SWB, social/family well-being; TRR, test-retest reliability.

ceed the 0.90 benchmark for clinical use of QoL instruments.¹⁰

TRR for both instruments was assessed by using the ICC based on a two-way mixed-effects model with absolute agreement. For the EORTC QLQ-C30, ICC values ranged from 0.75 to 0.89, indicating good to excellent temporal stability (Figure 4).²¹ As seen in Table 4 the ICC was 0.88 for PF, 0.85 for RF, 0.86 for EF, 0.89 for CF, and 0.75 for SF. For the FACT-G, ICCs ranged from 0.82 to 0.87, also supporting good to excellent TRT. Specifically, the ICC was 0.86 for PWB, 0.82 for SWB, 0.84 for EWB, and 0.87 for FWB (Table 5). The Bland–Altman analysis revealed a mean difference (bias) of 23.20 (95% CI: 21.87 to 24.53), indicating that, on average, the EORTC QLQ-C30 yielded higher HRQoL scores compared to the FACT-G across corresponding FDs (Figure 5).²²

Discussion

To our knowledge, this is the first study to cross-culturally adapt and psychometrically validate both the EORTC QLQ-

C30 and FACT-G for use in Bulgaria, including CSs from five tertiary hospitals. The findings provide robust evidence for the validity and reliability of the Bulgarian versions of both instruments in assessing HRQoL among Bulgarian CSs. While both questionnaires are widely used for evaluating HRQoL in cancer research, they are grounded in distinct conceptual frameworks. The EORTC QLQ-C30 was developed primarily for use in international clinical trials and emphasizes functional status and symptom burden, including physical, role, emotional, cognitive, and SF, along with key symptom domains such as fatigue, pain, and nausea.^{12,15} Its structure is aligned with the clinical trajectory of cancer treatment and recovery, making it highly sensitive to disease- and treatment-related impairments. In contrast, the FACT-G adopts a broader well-being-centered approach, focusing on patients' subjective perceptions of their physical, social/family, emotional, and FWB.^{8,16} This framework reflects a PRO concept that prioritizes emotional adjustment and QoL beyond purely clinical outcomes, which may be especially relevant in survivorship care. As such, FACT-G may be more suitable for assessing long-term

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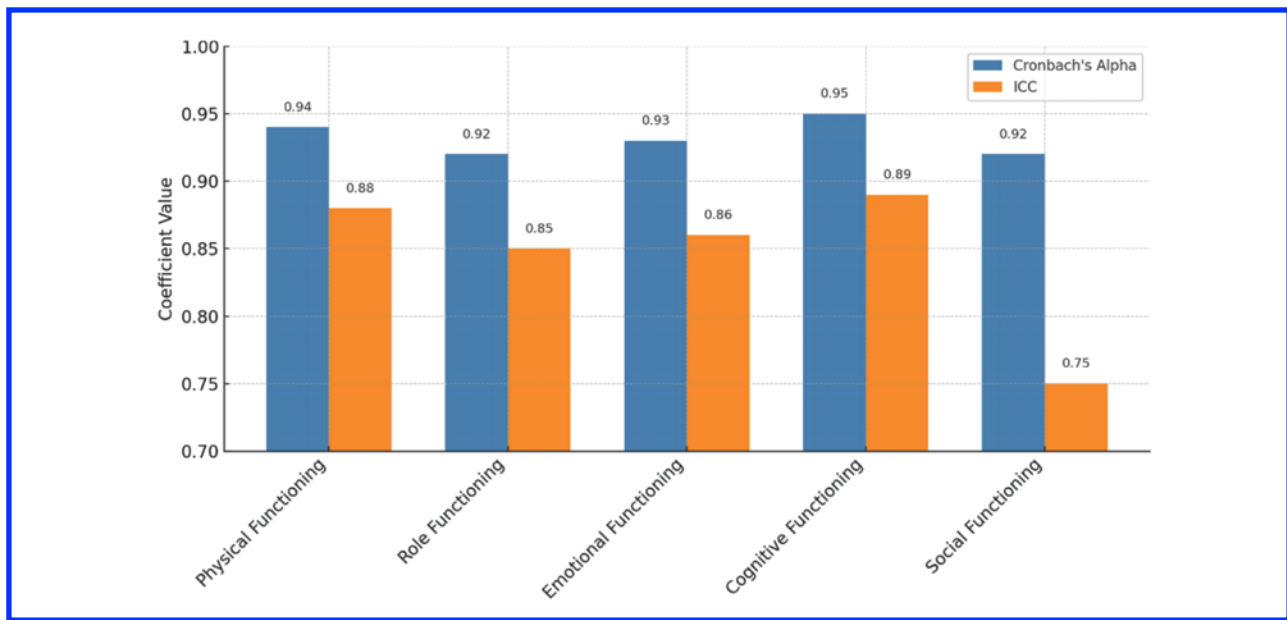


Figure 4. Internal consistency (IC) and test–retest reliability (TRR) for each of the five functional domains in the Bulgarian version of the EORTC QLQ-C30.

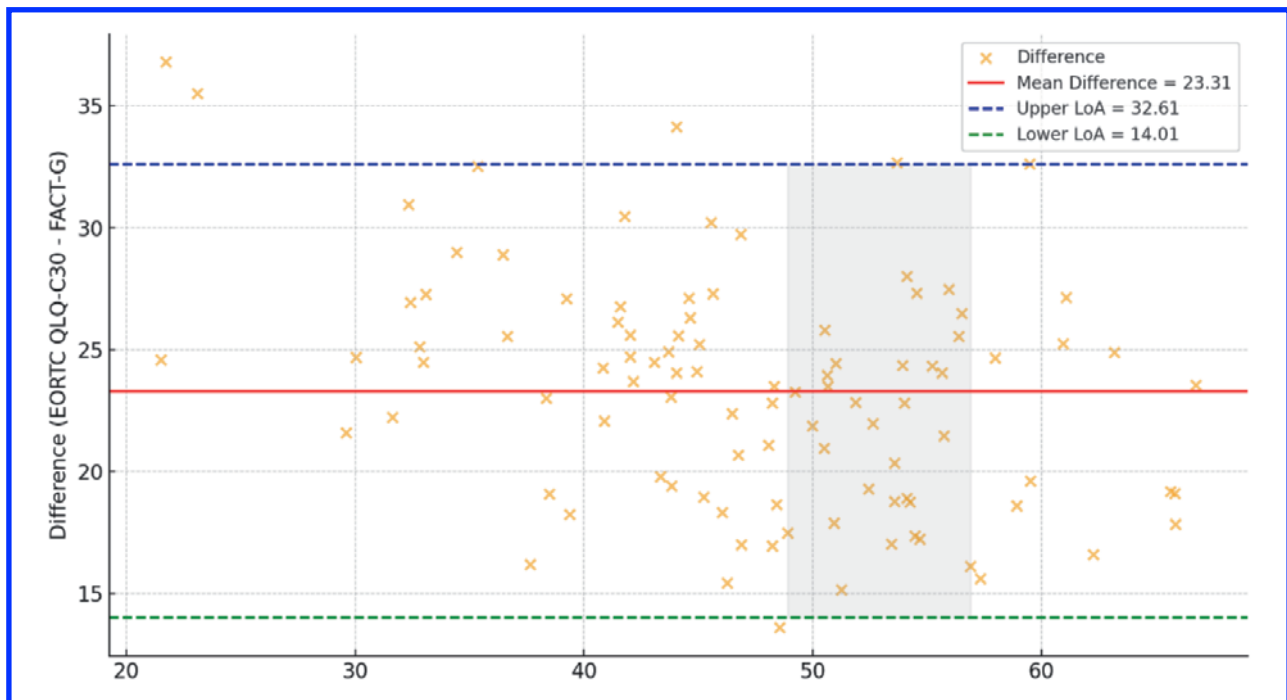


Figure 5. Bland–Altman analysis comparing the EORTC QLQ-C30 and FACT-G scores.

adaptation and well-being, whereas the EORTC QLQ-C30 may be more responsive to short-term treatment effects.^{14,20} These differences underline the complementary nature of both HRQoL instruments, and their combined use may provide a more comprehensive understanding of PRO across the cancer care continuum.²³

Psychometric evaluation revealed excellent IC across all domains, with Cronbach's α coefficients exceeding the recommended threshold of 0.70 and meeting or surpassing the 0.90 benchmark for clinical decision-making (Table 4; Table 5).²⁴ These results are consistent with prior validation studies conducted in diverse inter-

national settings, reinforcing the cross-cultural robustness of both instruments.^{13,14,18-20}

CV was supported through strong convergent and DV. High domain-level associations between the EORTC QLQ-C30 and FACT-G were particularly evident in the domains of PF, RF, and EF, indicating strong conceptual alignment across instruments (Table 2).²⁴ While these domains are inherently more subjective and potentially influenced by cultural attitudes toward psychological well-being and memory or concentration, the observed values suggest that both instruments assess these constructs with substantial agreement. Furthermore, the strong positive correlation ($r \approx 0.99$, $p < 0.001$) observed between the Bulgarian versions of the EORTC QLQ-C30 and the FACT-G reinforces their substantial CVg in evaluating HRQoL among CS. This finding aligns with previous cross-sectional validation studies that reported similarly high correlations between the instruments, supporting their complementary utility in both research and clinical settings.²⁵

While FE and CE are not direct indicators of responsiveness, substantial clustering at score extremes (typically >15%) suggests potential limitations in detecting further deterioration or improvement.²⁶ Moreover, the presence of mild CE in selected domains may attenuate responsiveness well-functioning Cancer Populations (CP).

TRR further confirmed the temporal stability of both instruments, with ICC values ranging from 0.75 to 0.89. Specifically, the EORTC QLQ-C30 demonstrated excellent temporal stability across most FD, with ICCs of 0.88 for PF, 0.85 for RF, 0.86 for EF, 0.89 for CF, and 0.75 for SF (Table 4). The FACT-G showed similar results, with ICCs ranging from 0.82 to 0.87 across its domains, also supporting its temporal reliability (Table 5). The relatively lower ICC observed for the SF domain in our study (ICC = 0.75) is consistent with findings from El Alami *et al.*²⁷, who reported an ICC of 0.64 for SF in the Moroccan version of the EORTC QLQ-C30, significantly lower than other FD. This trend underscores the transient and context-dependent nature of interpersonal and social experiences among CS.²⁰

The observed variability in SF scores of our study is thought to reflect the domain's heightened sensitivity to short-term emotional states, interpersonal dynamics, and contextual factors such as cultural and environmental influences.⁵ These findings are further supported by cross-cultural validation studies in diverse CP. Hoopman *et al.*²⁸ and Tomaszewski *et al.*,²⁹ reported similar patterns of lower TRR for SF domains, underscoring their susceptibility to transient psychosocial and cultural fluctuations. The measured 95% limits of agreement between the two HRQoL instruments, as revealed through Bland–Altman analysis, were within clinically acceptable bounds, indicating that the EORTC QLQ-C30 consistently yielded slightly higher HRQoL scores compared to the FACT-G (Figure 5). This discrepancy likely reflects inherent differences in scale structure, item phrasing, and response range, but it does not compromise the validity or clinical utility of either instrument.²²

This study has important implications for clinical prac-

tice in Bulgaria. First, the findings of this study offer Bulgarian oncologists, Surgical Oncologists SO, Physical and Rehabilitation Medicine PRM physicians, and other Healthcare Professionals HCPs involved in cancer care and survivorship a set of standardized, psychometrically robust, and culturally validated instruments for the assessment of PRO.^{11,23} Second, the study supports alignment with international recommendations, such as those from the European Society for Medical Oncology (ESMO), which advocate for the routine incorporation of HRQoL assessments into comprehensive cancer care and clinical decision-making. Third, it enhances the comparability of Bulgarian oncology data in multinational trials and collaborative studies.

Moreover, this validation effort supports the ongoing development of survivorship care in Bulgaria, which is increasingly prioritized due to improving survival rates. Reliable and culturally adapted tools for assessing HRQoL are essential for guiding individualized care, rehabilitation outcomes, and public health strategies. From a research standpoint, the availability of validated instruments lays the groundwork for future studies on symptom burden, late effects, and the long-term efficacy of behavioral and rehabilitation interventions.

The Bulgarian versions of the EORTC QLQ-C30 and FACT-G demonstrate strong psychometric properties, supporting their use in both clinical practice and research for CS in Bulgaria. Their combined application can provide a multidimensional perspective on PRO across different phases of the cancer care continuum.

Limitations

However, our study faced several limitations that should be acknowledged. First, the cross-sectional design precludes assessment of responsiveness to clinical changes over time.²⁶ Second, the sample included only CSs with lung, colorectal, and breast cancer, limiting the generalizability of findings to other cancer populations.

Third, while FACT-G was used as a comparator instrument, inclusion of additional validated HRQoL tools could have provided a more comprehensive concurrent validity assessment.¹⁴ Finally, another important limitation was that both the EORTC QLQ-C30 and FACT-G were simultaneously translated, adapted, and validated in this study. As neither tool had been previously validated in the Bulgarian CP, the CVg results must be interpreted with caution. Future research should aim to confirm these findings using external instruments that have already undergone psychometric evaluation in this context.

As neither instrument had been previously validated in this context, our assessment of CVg is constrained by the absence of an established reference standard. This parallel validation approach may limit the strength of conclusions regarding the observed cross-instrument correlations. Future studies should aim to validate these HRQoL instruments against other internationally recognized and previously validated tools, such as the SF-36 or EQ-5D, to further support their psychometric robustness and CVg.

Conclusions

The Bulgarian versions of the EORTC QLQ-C30 and FACT-G are valid, reliable, and culturally appropriate instruments for assessing HRQoL in Bulgarian CS. Both tools demonstrated excellent IC, strong CV, and good-to-excellent TRR. These findings support their use in clinical practice, survivorship programs, and research settings across Bulgaria. Future research should explore the responsiveness of both instruments over time and their applicability in broader CP.

List of abbreviations

BC, breast cancer
CCA, cross-cultural adaptation
CC, colorectal cancer
CCDs, cancer related deaths
CCV, cross-culturally validated
CF, cognitive functioning
CS, cancer survivors
CP, cancer populations
CV, construct validity
CVg, convergent validity
DV, discriminant validity
EF, emotional functioning
EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30
ESMO, European Society for Medical Oncology
EWB, emotional well-being
FACT-G, Functional Assessment of Cancer Therapy-General
FD, functional domains
FS-functional scales
FWB, functional well-being
HCPs, healthcare professionals
HRQoL, health-related quality of life
HS, health status
ICC, intraclass correlation coefficient
IC, internal consistency
LC, lung cancer
PRM, physical and rehabilitation medicine
PRO, patient-reported outcomes
PWB, physical well-being
QoL, quality of life
RF, role functioning
SF, social functioning
SO, surgical oncologists
SWB, social or family well-being
TRR, test-retest reliability

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Conflict of interest

The authors declare no financial, personal, or other conflicts of interest.

Ethics approval and consent to participate

All study participants signed written informed consent prior to enrollment, and all procedures were conducted in accordance with the Declaration of Helsinki (2013) and was approved by the Ethics Committee at the University Hospital «Sveta Marina», Pleven, Bulgaria, (Registry No. #223/13.10.2023).

Contributions

JP, GP, and HB contributed to the design, conception, data acquisition, analysis, and interpretation, as well as the writing and critical revision of the manuscript; JP, HB, and AU contributed to the writing and critical revision of the manuscript; GP, AU, PU contributed to the design and has been involved in the critical revision of the manuscript; JP, YK, GG and KP contributed to data analysis and interpretation and has been involved in the critical revision of the manuscript; MB, YK, GG, DS contributed to the analysis and interpretation as well as critical revision of the manuscript; ND, HB, DS, and YK contributed to the analysis and interpretation as well as critical revision of the manuscript. All authors read and approved the final manuscript.

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