



Translation and Validation of a Vietnamese Version of the Colorectal Cancer Subscale for the Functional Assessment of Cancer Therapy - Colorectal Questionnaire

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Abstract

Introduction: There is a need for a validated Vietnamese translation of the colorectal cancer subscale (CCS) of the functional assessment of cancer therapy–colorectal (FACT-C) questionnaire to assess colorectal cancer-specific concerns of Vietnamese persons with colorectal cancer post-surgery.

Objectives: This study aims to translate and validate the CCS of FACT-C questionnaire in Vietnamese persons with colorectal cancer post-surgery.

Methods: The nine-item CCS was translated following the functional assessment of chronic illness therapy (FACIT) translation methodology guidelines. Psychometric properties of a Vietnamese version of the CCS were evaluated with a sample of 135 participants who were randomly selected from three hospitals in Vietnam, utilizing a multistage sampling method. Construct validity was examined through confirmatory factor analysis (CFA), and reliability was assessed using Cronbach's α coefficients. These measures aimed to validate the psychometric properties of the Vietnamese nine-item CCS version. Descriptive statistics were used to analyze participant demographics with SPSS.

Results: The translated version demonstrated equivalence to the original English version. CFA results for the CCS Vietnamese version indicated that all 9 items were consistent with a unidimensional questionnaire ($\chi^2 = 69.669$, $p > .05$, $df = 27$, $\chi^2/df = 2.58$, $RMSEA = .074$, $CFI = .917$, $TLI = .901$, $SRMR = .057$). The Cronbach's α coefficient was .86, indicating high reliability. The Correlated Item-Total Correlation for the 9 items ranged from .39 to .76.

Conclusion: The nine-item CCS Vietnamese version demonstrated appropriate translation, establishing its validity and reliability in measuring colorectal cancer-related concerns within the health-related quality of life among Vietnamese persons post-surgery.

Keywords

FACT-C, health-related quality of life, colorectal cancer subscale, scale translation, scale validation

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Introduction

Colorectal cancer (CRC) is the fifth most common cancer in Vietnam, accounting for 9% of new cancer cases among 16,426 individuals diagnosed with the disease. The incidence rates for colon and rectum cancer are 3.5% and 5.1%, respectively. The high mortality rates lead to the loss of 4758 individuals annually to rectum cancer and 3445 to colon cancer (World Health Organization, 2020). Additionally, researchers predict an 18.6% rise in the occurrence of common cancers in Vietnam by the year 2025 (Minh et al., 2019).

Surgery is the standard and primary treatment for most CRC patients in Vietnam (Le et al., 2021; Tran et al., 2020). However, this treatment modality is associated with

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various side effects that significantly impact patients' quality of life, leading to a diminished health-related quality of life (HRQL) (Chinh et al., 2019; Dung et al., 2021; Huyen et al., 2021). Hence, the overarching treatment goal is to enhance patients' HRQL.

Review of Literature

The functional assessment of cancer therapy-colorectal (FACT-C) emerges as a suitable self-reported questionnaire to assess HRQL for specific colorectal cancer patients. The FACT-C questionnaire comprises 27 items from the FACT-G and 9 items from the Colorectal Cancer Subscale (CCS). Currently available in over 50 languages, the FACT-C scale allows for cross-cultural comparisons among individuals from diverse backgrounds (El-Badawy et al., 2018). It is utilized to evaluate CRC patients at various stages, including pre-surgery (Nair et al., 2014), one month and six months post-surgery (Yoo et al., 2005), and CRC post-surgery (Ilic-Zivojinovic et al., 2022; Sharma et al., 2007; Wilson et al., 2006). Validation studies conducted in China (Yu et al., 2000), Korea (Yoo et al., 2005), Egypt (El-Badawy et al., 2018), and the United States (Ward et al., 1999) have confirmed that FACT-C is a qualified instrument for measuring HRQL in CRC patients.

As a component of FACT-C, the FACT-G was developed as a part of the Functional Assessment of Chronic Illness Therapy (FACIT) and validated by the original author, Cella et al. (1993). Moreover, the FACT-G has been translated into various languages, including Vietnamese, following the FACIT standardized method and validated for individuals with various types of cancer (Brucker et al., 2005). The Vietnamese version of FACT-G evidences good reliability and validity (Nguyen, 2018; Tieu Mai et al., 2020).

However, the remaining component of FACT-C, the CCS, has not been available in the Vietnamese. Therefore, it is necessary to validate the appropriateness of CCS within the context of Vietnamese culture. Since there is currently no questionnaire designed to assess health-related quality of life specifically for colorectal cancer, the CCS Vietnamese version could facilitate research on the health-related quality of life among Vietnamese persons with colorectal cancer. Consequently, this study aims to translate and validate the CCS of the FACT-C scale among Vietnamese persons with CRC post-surgery.

Methods

Study Design

Data for this study were extracted from as a part of a cross-sectional study titled "A causal model of health-related

quality of life among persons with colorectal cancer post-surgery in Vietnam".

The instruments included a general information form and FACT-C. The general information form included age, gender, family status, education, employment status, height, usual weight, current weight, duration from surgery, disease stage, type of cancer, type of stoma, and type of treatment. The CCS, a component of FACT-C, comprises 9 items assessing specific colorectal cancer issues. Each item is rated on a five-point Likert scale (not at all, a little bit, somewhat, quite a bit, very much).

Sample

Participants were recruited from oncology centers of three hospitals in Vietnam, employing a multistage sampling method.

Considering the sample size, factor analysis requires a rule of 10 or 15, with at least 10 cases for each item in the instrument used (DeVellis, 2017). Since the CCS consists of nine items, the sample size in this study should range from 90 to 135. Correspondingly, Hair et al. (2010) recommended a sample size of at least 100 cases to conduct a factor analysis. Thus, 135 respondents were selected in this study. Participants provided written informed consent and completed the questionnaires while awaiting health check results or the subsequent chemotherapy cycle in the hospital.

Inclusion Criteria

Inclusion criteria were individuals aged 20 to 59, having undergone CRC surgery for the first time as the primary treatment, 1 to 6 months post-surgery, without prior cancer surgery, and capable of reading and verbally communicating in Vietnamese.

Exclusion Criteria

The participants were excluded if presenting potentially life-threatening or widespread metastases (for example, tumors metastasized to the brain, liver, etc.)

Institutional Review Board

Before starting to collect the data, the researcher had approached the Ethics Committee of three hospitals in Vietnam. Afterward, the researcher obtained ethical approval from the Institutional Review Board (IRB) (No. 1909/BVK-HDDD, 894/GCN-HDD, and 2013/QD-BVUB) and received permission from the Institutional Ethics Committee to approach the participants through the nurses in the hospitals. Consent was also provided for the protection of the participants who met all of the inclusion criteria and who were willing to join this study.

Data Collection

The data was collected from May to August 2023. Three research assistants, who were head nurses from three hospitals, underwent training on the study's objectives, methodology, tools, ethical considerations, and data collection procedures. They then selected appropriate participants and assisted in introducing them to the researcher. Subsequently, the researcher held a private meeting where they explained the study's goals, assured confidentiality, and obtained signed consent forms from the participants who agreed to take part in the research. The participants completed a self-administered questionnaire, which took about 30 min to finish.

Statistical Analysis

Data analysis for this study utilized SPSS version 29 and Mplus version 8.3. Descriptive statistics were employed to analyze the demographic characteristics of the participants. Construct validity and reliability were assessed to confirm the psychometric properties of the Vietnamese version of CCS. Confirmatory Factor Analysis (CFA) was utilized for examining construct validity, with five statistical criteria employed to evaluate the model fit: non-significant chi-square (χ^2) ($p > .05$), normed Chi-squared (χ^2/df) was < 3 , root mean square error of approximation (RMSEA) $\leq .08$, comparative fit index (CFI) and Tucker–Lewis index (TLI) $> .90$, standardized root mean square residual (SRMR) was $< .08$ (Byrne, 2013). Internal consistency of

Table 1. Demographic Characteristics of the Participants (n = 135).

Data	n	Percent
Age (years)		
20–29	7	5.20
30–39	21	15.55
40–49	21	15.55
50–59	86	63.70
Mean (SD) = 49.30 (10.20)		
Gender		
Male	80	59.26
Female	55	40.74
Family status		
Married	128	94.81
Single	7	5.19
Education		
Primary school	13	9.63
Secondary school	54	40.00
High school	45	33.33
College	15	11.11
University or higher	8	5.93
Employment status		
Unemployed	73	54.07
Employed	62	45.93

the CCS Vietnamese version was assessed using Cronbach's alpha coefficients, with values above .70 considered acceptable (DeVellis, 2017).

Translation Process

The translation process involved four experts: two Vietnamese lecturers with a doctoral nursing program abroad, possessing English certificates, and have been working in oncology nursing field for at least 5 years; one Vietnamese professional translator, an English lecturer in a nursing university; and one Vietnamese practice nurse with experience in an Australian hospital.

With permission from the FACIT.org teams and the requirement of the developers, the 9-item CCS was translated following the FACIT translation methodology guidelines (Eremenco et al., 2005). The process included six main steps:

1. Two independent forward translations from English to Vietnamese by two Vietnamese oncology nurses.
2. Selection of one translated version by comparing and combining two forward translations by a Vietnamese professional translator.
3. Blind back-translation from Vietnamese to English by a Vietnamese practice nurse working in an English-native country.
4. Review and comments from FACIT.org teams on the back-translated version.
5. The author and a Vietnamese professional translator resolved all the comments until getting agreement from FACIT experts.
6. The FACIT staff formatted the test versions for pilot testing and the researcher proofreading the final Vietnamese version.

Once the test form was approved, a pilot study was conducted. Ten individuals who had undergone colorectal cancer surgery within the past 1 to 6 months randomly selected from the Oncology department at a general hospital. These participants provided feedback on the conceptual clarity of the Vietnamese version. The final version was approved for use in the main study through a copyright granted by FACIT.org teams.

Results

Sample Characteristics

In a total of 135 participants without any missing data, 59.26% (80 out of 135) were male, with a mean age of 49.30 years (SD = 10.20), and the majority (63.70%) falling within the 50–59 years age group. A significant proportion were married (94.81%). Approximately half of participants had secondary school education (40.00%) and high school education (33.33%). Employment status indicated that 54.07% were unemployed. Most patients were at

stage III (62.22%) and diagnosed with colon cancer (69.63%). The majority did not have a stoma (80.00%), and 86.67% underwent surgery combined with chemotherapy. The mean of duration from surgery was 3.40 months (SD = 1.60) (Tables 1 and 2).

Translation and Pilot Testing

During pilot testing, participants indicated a clear understanding of the Vietnamese questionnaire, finding all items easy to rate. Participants expressed satisfaction with the questionnaire, and no recommendations for additional information were made. Following feedback from FACIT, the final translated version incorporated the term “lỗ mở thông” (“ostomy appliances”) instead of “hậu môn nhân tạo” (“stoma”). With this modification, participants confirmed their understanding. The final version was approved after pilot testing without further changes.

Table 2. Clinical Characteristics (n = 135).

Data	n	Percent
Disease stage		
Stage I	7	5.19
Stage II	29	21.48
Stage III	84	62.22
Stage IV	15	11.11
Type of cancer		
Colon cancer	94	69.63
Rectum cancer	41	30.37
Type of stoma		
Non-stoma	108	80.00
Permanent stoma	21	15.56
Temporary stoma	6	4.44
Type of treatment		
Surgery with chemotherapy	117	86.67
Surgery with radiotherapy	1	0.74
Surgery only	17	12.59
Duration from surgery (months)		
Mean (SD) = 3.40 (1.60)		

Table 3. Item Description and Reliability.

Item No.	Item content	Mean ± SD	Correlated Item-Total Correlation	Cronbach's Alpha if Item Deleted
C1	I have swelling or cramps in my stomach area	2.67 ± 0.48	0.72	0.81
C2	I am losing weight	2.44 ± 0.50	0.67	0.81
C3	I have control of my bowels	2.67 ± 0.48	0.76	0.79
C4	I can digest my food well	2.63 ± 0.49	0.39	0.83
C5	I have diarrhea (diarrhoea)	2.67 ± 0.48	0.48	0.82
C6	I have a good appetite	2.14 ± 0.36	0.46	0.82
C7	I like the appearance of my body	2.44 ± 0.51	0.74	0.80
C8	I am embarrassed by my ostomy appliance	3.15 ± 0.36	0.59	0.81
C9	Caring for my ostomy appliance is difficult	3.22 ± 0.42	0.61	0.81

Psychometric Properties

Reliability. The reliability analysis, as measured by Cronbach's α for the CCS Vietnamese version, yielded a value of .86, falling within the range considered adequate to good. Additionally, the Correlated Item-Total Correlation for the 9 items ranged from .39 to .76. This range indicates very good discrimination, surpassing the recommended threshold of .30 (Nunnally & Bernstein, 1994) (see Table 3).

Construct Validity. These findings indicated that the 9-item CCS Vietnamese version demonstrated a good fit with a unidimensional structure, supporting its validity for measuring colorectal cancer-related concerns in the Vietnamese population post-surgery ($\chi^2 = 69.669$, $p > .05$, $df = 27$, $\chi^2 / df = 2.58$, RMSEA = .074, CFI = .917, TLI = .901, SRMR = .057). Most items in the CCS Vietnamese version demonstrated standardized estimations (factor loadings) exceeding .40, indicative of a strong association with the underlying construct (see Figure 1).

However, two items C8, and C9 - had lower factor loadings at .179, and .309, respectively. Notably, items C8 and C9 pertained to ostomy appliances: “I am embarrassed by my ostomy appliance”; and “Caring for my ostomy appliance is difficult”. These items were exclusively relevant to patients with ostomies, representing a small percentage of all colorectal cancer patients in the study (27 out of 135 cases, or 20.00%). Despite the lower factor loadings, these items were retained in the final model.

Discussion

This study aimed to translate and assess the psychometric properties of the CCS Vietnamese version of FACT-C for Vietnamese patients with CRC post-surgery. The results demonstrated that the Vietnamese version of CCS was easily understood, culturally appropriate, and equivalent to the English version. The CCS Vietnamese version truly reflects the colorectal cancer-specific concerns with good psychometric validity and good internal consistency. The confirmatory factor analysis confirmed that the 9 items formed a unidimensional questionnaire accurately measuring specific colorectal cancer-related

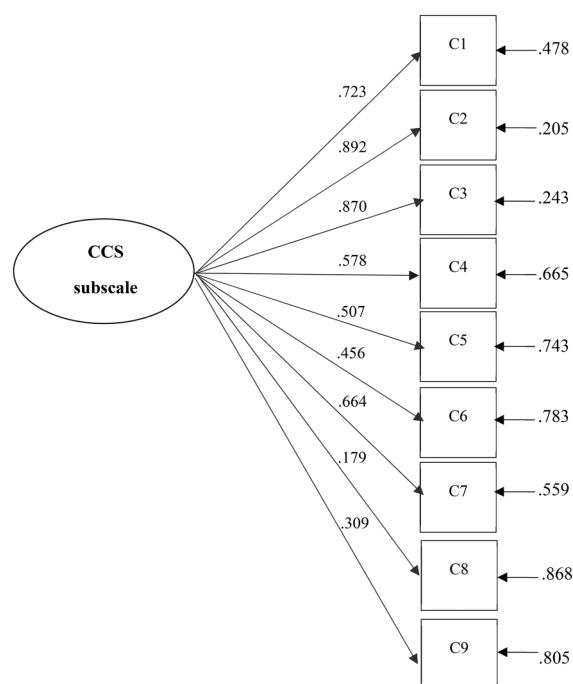


Figure 1. Construct Validity of CCS from 135 CRC Post-Surgery Patients.

concerns on FACT-C for Vietnamese CRC patients. These findings were consistent with previous studies (Ward et al., 1999), which reported that these heterogeneous items were included on a scale due to their unique relation to CRC patients and supported a comprehensive assessment of HRQL for persons with colorectal cancer.

The internal consistency of the CCS Vietnamese version, indicated by Cronbach's α of .86, was within a good range. This finding was consistent with the original version which illustrated Cronbach's α for the 9-item CCS was .61 in the ostomy sample, .76 for the 7-item CCS in colorectal cancer, .85 for the FACT-C including 9-item CCS in general (Ward et al., 1999); and those of other language adaptations such as the French CCS (Cronbach's α of .81) (Rotonda et al., 2008), and the traditional Chinese CCS (Cronbach's α of .68) (Wong et al., 2012), supporting the reliability of the scale across different cultural contexts. The slight increase in internal consistency in the Vietnamese version may be attributed to cultural differences.

In confirmatory factor analysis, while two items had factor loadings lower than .40, the study revealed consistency in internal consistency between the 9-item and 7-item versions. There was no significant change in the value of alpha change if item deleted method, the 9-item CCS was recommended to apply to all colorectal cancer patients.

Strengths and Limitations

This study represents the first assessment of health-related quality of life in Vietnamese language among colorectal

cancer patients, including both those with and without stomas. The results demonstrated strong psychometric properties. However, a limitation is the challenge of evaluating CRC patients with stoma due to the limited number of stoma patients in the Vietnamese context. Further research focusing specifically on patients with ostomy appliances is warranted to comprehensively understand the impact of CRC-specific issues in this subgroup. Additionally, for a more comprehensive understanding of CRC post-surgery care, further investigations are necessary.

Implications for Practice

Since there is currently no measurement for health-related quality of life for Vietnamese individuals with colorectal cancer, having an accurate, feasible, and practical assessment tool is crucial to maintain high-quality nursing care and improve the quality of life for colorectal cancer patients. Therefore, it is essential to have a validated tool specifically designed to assess health-related quality of life in Vietnamese individuals with colorectal cancer for evaluating post-treatment functionality. This tool can be regularly used in clinical settings to identify key concerns during the care of colorectal cancer patients and to enhance quality-of-life interventions for this population.

Conclusions

The study found that the CCS Vietnamese version of FACT-C version 4 was suitable and adheres to standard translation methodology, demonstrating good psychometric validity and internal consistency. This tool holds value for healthcare professionals in identifying colorectal cancer-related concerns among Vietnamese post-surgery persons and could help in establishing targeted goals to improve their health-related quality of life.

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Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author's Contributions Statement

1. Tran Thi Hong Hanh: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Software, Validation, Visualization, Writing – original draft, Writing - review & editing.
2. Sureeporn Thanasilp: Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology,

Project administration, Resources, Supervision, Validation, Writing – original draft, Writing - review & editing.

- Noppamat Pudtong: Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Resources, Supervision, Validation, Writing – original draft, Writing - review & editing.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethics Approval and Consent to Participate

This study was approved by the Institutional Review Board of Nam Dinh University of Nursing, Vietnam with study approval number approval 894/GCN-HĐĐĐ, by the Institutional ethic committee of Vietnam National Cancer Hospital with study approval number approval 1909/BVK-HĐĐĐ, and by the Institutional ethic committee of Hanoi Oncology Hospital, Vietnam with study approval number approval 2013/QĐ-BVUB. Written informed consent was obtained from all participants prior to their participation in the study.

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Study Approval Number

The study was approved by the Board of the Faculty of Nursing, Chulalongkorn University No. 5/2023 Date March 7, 2023.

Supplemental Material

Supplemental material for this article is available online.

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