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Validation of a Questionnaire to Delineate the Clinical Trial Nursing Roles in Korea

KEY WORDS

Clinical trial
Korea
Nursing role
Validation study

Background: In clinical trials, research nurses play a particularly important role in promoting cancer care best practices. However, no Korean questionnaire has been developed to define the clinical trial nursing roles based on Good Clinical Practice standards. **Objective:** The aim of this study was to cross-culturally evaluate the reliability and validity of a Korean version of the Clinical Trials Nursing Questionnaire (CTNQ) among Korean clinical research nurses. **Methods:** Cross-cultural adaptation was performed, with forward and backward translation, a pilot test (linguistic validation), and a field test. Validation was performed by questioning 53 clinical research nurses who were working in clinical cancer centers at 5 tertiary university hospitals. The distribution of the item responses and internal consistency reliability were assessed using the ceiling and floor effects, Cronbach's α , and the item-total correlation. Construct validity was assessed using Spearman correlation analysis and principal-component factor analysis. **Results:** The distributions of the item responses and the item-total correlation were generally appropriate. The Cronbach's α values for the frequency scale and the importance scale were 0.852 and 0.899, respectively. Eight sections of the Korean CTNQ were generally correlated with each other. The frequency subscale loaded on 1 factor, and the importance subscale loaded on 2 factors, with broadly similar factor loadings. **Conclusion:** The Korean version of the CTNQ is reliable, valid, and interchangeable with the original CTNQ. **Implications for Practice:** The Korean version of the CTNQ can be used to validly and reliably assess the clinical trial nursing roles in Korea.

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The Korean infrastructure for clinical trial registration has markedly improved since the introduction of the Good Clinical Practice (GCP) standards in the early 2000s.¹ In this context, clinical trials are recognized by the Korean government as important tools in promoting future healthcare technology for new drug development and cancer care best practices.² In addition, steps are being taken to ensure the globalization of clinical trials, including the establishment of centers of excellence, development of educational and training programs for clinical trials professionals, formation of international accreditation of ethics committees, and early regulatory reformation of the old drug approval system to ensure it is in accordance with the International Committee of Harmonization guidance.¹⁻³ Furthermore, the number of investigational new drug approvals and multinational clinical trials has increased considerably, and among these trials, the most commonly tested treatment in 2015 was anticancer drugs (255 trials, 37.8%).³ Between 1999 and 2011, 1 097 253 patients in Korea received a diagnosis of cancer, and cancer-related mortalities have increased steadily, accounting for 27.6% of all mortalities in 2012.⁴ Despite the overall cancer incidence rates rapidly increasing by 3.4% per year during the past 13 years, the overall cancer mortality rates have declined since 2002, and the survival rate has improved with the development of early detection methods and more effective treatments.⁴

Clinical research nurses (CRNs) are specially trained staff nurses who are responsible for safeguarding the research subjects and maintaining the integrity of the research protocol.⁵ In addition, it is widely acknowledged that the quality of clinical research is greatly improved when nurses are involved at the investigators' site.⁶ Given that clinical research trial participation has been opened to broader patient populations, as well as cancer patients, CRNs have become essential members of the clinical research team and are responsible for many roles and aspects of clinical trial management.⁷ The responsibilities of nurses in conducting research range from the collection and recording of data to recruitment and screening of patients, ensuring informed consent, drug randomization, following up with patients, and staff development and training to meet the required international standards.⁶ To meet these demands, it is critical to have research personnel with an appropriate skill mix to ensure that clinical trials are conducted safely and effectively while maintaining their scientific integrity.⁸ However, research personnel must be provided with education, training, and support for their expanding responsibilities.⁹ In addition, further work is needed to develop an understanding of how nurses engage with their role functions and how we can measure these role activities.¹⁰

The Clinical Trials Nursing Questionnaire (CTNQ) was originally developed in American English,¹¹ based on the Nursing Role Effectiveness Model, to facilitate the identification and investigation of nursing-sensitive outcomes and their achievement, as a basis for evaluating clinical nurse specialists' practice and monitoring their improvements in clinical practice.¹⁰⁻¹² This tool includes 3 components: structure (professional nursing role perception, role characteristics, organizational characteristics, and demographics), process (frequency scale and

importance scale of the CRNs' role), and outcomes (GCP guidelines enactment).^{11,12} The original CTNQ tool was developed using literature review, conceptualization of the subscales, development of items for each subscale, development of the tool, expert judging panel evaluation, focus group testing, administration of the tool, and psychometric analysis. In this context, it is identified as a self-assessed instrument, which is reliable, valid, and comprehensive and reflects the entire spectrum of clinical trial nursing roles.¹¹ The Italian version of the CTNQ has also been proven to be reliable and valid.¹³

The specific role of the oncology nurse in clinical trials had been defined years ago, and oncology nursing is currently becoming an emerging profession.¹³ However, despite the expanding role of nurses in Korean clinical cancer research, there are few systematic, consistent, and qualified programs for their training. Furthermore, the existing programs were not established for assessing and evaluating the scope and contribution of the CRN role based on the enactment of GCP standards.¹⁴⁻¹⁶ Finally, no Korea-specific questionnaire exists for assessing and evaluating the clinical trial nursing roles. Therefore, a measure must be developed to establish the general competencies that are required for basic and advanced levels of practice in clinical research, and this measure should be developed in a large, diverse population of nurses who are working in the research setting.¹²

In this study, we developed a Korean CTNQ and evaluated its reliability and validity. During this process, we focused on the translation to ensure clear, precise, and equivalent duplication of the original CTNQ, and this was facilitated by rigorous validation steps, which included forward translation, backward translation, a formal comparison of the forward-backward translation against the original, a pilot test for linguistic validation, and a final field testing for psychometric evaluation.¹⁷ Therefore, the objectives of this study were to translate the original CTNQ into the Korean language (linguistic validation), to evaluate its ceiling and floor effects and internal consistency reliability via Cronbach's α and the item to total correlations, and to determine its validity via convergent validity and factor analysis.

■ Methods

Study Design

This study used a psychometric validation design to evaluate the reliability and validity of the Korean version of the CTNQ, which is composed of 12 sections with 151 items (Table 1).

Setting and Samples

This study was conducted at 5 clinical trial research centers at tertiary university hospitals in Seoul and Gyeonggi-do, Korea. To estimate the required sample size for convergent validity according to the point biserial correlation model, we used the G*Power 3.1.7 program (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany)¹⁸ with a 2-sided test ($\alpha=0.05$), a power of

**Table 1 • Format of the English and Korean Clinical Trials Nursing Questionnaire**

Section	Number of Items	
	English	Korean
1. PA	Frequency	Importance
2. PP	Frequency	Importance
3. SR	Frequency	Importance
4. ICP	Frequency	Importance
5. IP	Frequency	Importance
6. IE	Frequency	Importance
7. DM	Frequency	Importance
8. PN	Frequency	Importance
9. Professional nursing role perception		
10. Professional nursing role characteristics		
11. Organizational characteristics		
12. Demographic information		
Total sections/items	12	154

Abbreviations: PA, protocol assessment; PP, protocol planning; SR, subject recruitment; ICP, informed consent process; IP, investigational product management; IE, implementation and evaluation; DM, data management; PN, professional nursing role performance.

1- β of 0.80, and an anticipated difference (effect size) of 0.40. Based on these calculations, the minimum sample size was calculated to be 44 participants. Therefore, we recruited 70 CRNs who were working for these clinical trial centers as clinical research coordinators; of these, 53 nurses agreed to participate in this study, and these participants subsequently completed the Korean CTNQ. This sample size (N=53) is considered barely adequate for evaluating the psychometric properties of measures for social constructs via factor analysis,¹⁹ and this represents a limitation of this study. Details regarding the professional nursing role, organizational, and demographic characteristics of the 53 participants are presented in Table 2.

Ethical Considerations

Information regarding the study was given to each eligible nurse, and their informed consent was obtained. The study protocol and all study procedures were approved by the Graduate School Proposal Review Committee of CHA University.

Measurement: The CTNQ

The original CTNQ has 12 sections with a total of 154 items. Sections 1 to 8 for performance (frequency) and importance contain 120 items that comprise a comprehensive assessment of clinical research nursing activities and responsibilities. Responses for all frequency questions regarding which activities that the CRN had performed during the previous year were coded as follows: 0, never or not part of my role; 1, once or twice; 2, occasionally or as needed; 3, repeatedly or at various times; and 4, extremely frequently. The responses for all importance questions (which indicate the importance of the activity for the safety and effectiveness of the clinical trial nursing practice) were coded as follows: 0, not important; 1, somewhat important; 2, important; 3, moderately important; and 4, very important. Section 9 (10 items) examines the respondent's perceptions and experiences related to the roles of a CRN using a 5-point Likert-type scale. Scores range from 1 (strongly agree)

to 5 (strongly disagree), and "not applicable" is considered an acceptable response. Section 10 (11 items) contains questions regarding the professional characteristics of the nursing roles. Section 11 (9 items) consists of questions regarding the nurse's employer or organization. Finally, section 12 (4 items) contains questions regarding the demographic characteristics of the professional nurse.¹¹ Each section (sections 1-8) for the frequency and importance subscales was evaluated using a scale of 0 to 4, with a lower score indicating less frequent and important CRN roles.^{11,13} The final scores for the performance (frequency) and importance subscales were then defined by calculating the mean scores for sections 1 to 8 in the Korean CTNQ.

Translation and a Pilot Test (Linguistic Validation)

We obtained written approval for developing a Korean version of the CTNQ from the developer and received the original questionnaire in English. We used rigorous international translation steps based on Fayers and Marchin's¹⁷ guidelines, and 2 trained bilingual Koreans independently translated the original English CTNQ into Korean. To evaluate the conceptual equivalence and consistency of the items and response choices, a group of specialists (including 2 CRNs, a research coordinator, and a biostatistician) compared the 2 translations and reconciled any discrepancies until an acceptable equivalence was obtained. After we completed the forward translation, 2 other translators who were fluent in English and Korean independently translated the Korean version of the CTNQ back into English, and the 2 backward translations were then compared with the original CTNQ for conceptual consistency.

A pilot test was conducted with 10 CRNs who completed the Korean CTNQ (151 items); these CRNs did not participate in the field test. In the pilot test, we examined whether the respondents found any of the translated items confusing, difficult to understand, ambiguous, or annoying. In addition, we assessed the internal consistency reliability using Cronbach's α , which is the most commonly used method for assessing the reliability of continuous data with 4 or 5 response categories.¹⁷

Table 2 • Professional Nursing Role Perception, Role Characteristics, Organizational Characteristics, and Demographic Information of Korean Clinical Trial Research Nurses (N=53)

Characteristics	Category	n (%) or M±SD
Professional nursing role perception		2.50±0.41
Professional nursing role characteristics		
Highest nursing degree you have completed	Associate	14 (26.4)
	Bachelor's	37 (69.8)
	Master's	2 (3.8)
Highest nonnursing degree you have completed	Associate	3 (5.7)
	Bachelor's	4 (7.5)
	None	46 (86.8)
If certification in clinical research nursing became available, would you pursue it?	Yes	41 (77.4)
	No	1 (1.9)
	Uncertain	11 (20.8)
Was your primary education and training in clinical research mostly formal or informal?	Mostly formal	40 (75.5)
	Mostly informal	13 (24.5)
How many clinical trial–specific continuing education programs have you attended in the past year?	1	21 (39.6)
	2	16 (30.2)
	3–5	16 (30.2)
	None	5 (9.4)
What type of clinical trial(s) you are involved in?	Phase I trials	11 (20.8)
	Phase II trials	32 (60.4)
	Phase III trials	46 (86.8)
	Phase IV trials	35 (66.0)
	SIT	30 (56.6)
	IIT	41 (77.4)
How often are you identified as a subinvestigator for a clinical research study?	Never	10 (18.9)
	Sometimes	22 (41.5)
	Frequently	21 (39.6)
How often are you identified as a principal investigator for a research study?	Never	29 (54.7)
	Sometimes	19 (35.8)
	Frequently	5 (9.4)
Clinical nursing experience, y		3.36±3.05
Experience as a CRN, y		2.25±1.52
Organizational characteristics		
Employment status	Full time	50 (94.3)
	Part time	3 (5.7)
Primary work setting	Multihospital system	25 (47.2)
	Physician office	24 (45.3)
	Contract research organization	4 (7.5)
Is a description of your position available?	Yes	26 (49.1)
	No	27 (50.9)
Are standard operating procedures relevant to your position?	Yes	34 (64.2)
	No	19 (35.8)
Do you have a career ladder for professional development?	Yes	22 (41.5)
	No	31 (58.5)
Immediate supervisor	Physician	23 (43.4)
	Nurse	22 (41.5)
	Other	8 (15.1)
Position title	CRA	36 (67.9)
	CRN	17 (32.1)
Demographic information	Female/male	52 (98.1)/1 (1.9)
	Age, y	30.25±4.66

Abbreviations: M±SD, mean±SD; SIT, sponsor-initiated trial; IIT, investigator-initiated trial; CRN, clinical research nurse; CRA, clinical research associate.

We assessed the convergent validity using Spearman correlation coefficients between the 8 sections of the CTNQ. The Korean translation was then refined and finalized by rewording several of the items and the response choices based on respondents' feedback. However, the small sample size (n=10)

limited this test's ability to estimate internal consistency or assess item performance, although a sample 10 or less may be sufficient for assessing the instructions' clarity or item wording, formatting acceptability, and ease of administration.²⁰ The final Korean version of the CTNQ contained

 **Table 3 • Spearman Correlation Coefficients for Convergent Validity**

Subscales	PA	PP	SR	ICP	IP	IE	DM	PN
Pilot test (n = 10)								
Frequency and importance								
PA	—							
PP	0.68 ^a	—						
SR	0.53 ^a	0.58 ^a	—					
ICP	0.50 ^a	0.64 ^a	0.46 ^a	—				
IP	0.41 ^a	0.56 ^a	0.31 ^b	0.77 ^a	—			
IE	0.38 ^a	0.59 ^a	0.48 ^a	0.76 ^a	0.65 ^a	—		
DM	0.38 ^a	0.58 ^a	0.36 ^a	0.80 ^a	0.65 ^a	0.79 ^a	—	
PN	0.36 ^a	0.41 ^a	0.43 ^a	0.50 ^a	0.36 ^a	0.52 ^a	0.56 ^a	—
Field test (n = 53)								
Frequency								
PA	—							
PP	0.65 ^a	—						
SR	0.59 ^a	0.64 ^a	—					
ICP	0.29 ^b	0.25	0.47 ^a	—				
IP	0.38 ^a	0.35 ^a	0.31 ^b	0.47 ^a	—			
IE	0.28 ^b	0.32 ^b	0.34 ^b	0.56 ^a	0.59 ^a	—		
DM	0.42 ^a	0.51 ^a	0.55 ^a	0.52 ^a	0.41 ^a	0.55 ^a	—	
PN	0.43 ^a	0.53 ^a	0.38 ^a	0.22	0.37 ^a	0.27	0.41 ^a	—
Mean of frequency	0.70 ^a	0.71 ^a	0.73 ^a	0.67 ^a	0.70 ^a	0.69 ^a	0.78 ^a	0.50 ^a
Importance								
PA	—							
PP	0.68 ^a	—						
SR	0.53 ^a	0.57 ^a	—					
ICP	0.45 ^a	0.63 ^a	0.42 ^a	—				
IP	0.41 ^a	0.58 ^a	0.30 ^b	0.77 ^a	—			
IE	0.37 ^a	0.56 ^a	0.46 ^a	0.73 ^a	0.67 ^a	—		
DM	0.37 ^a	0.58 ^a	0.33 ^b	0.74 ^a	0.68 ^a	0.78 ^a	—	
PN	0.38 ^a	0.43 ^a	0.44 ^a	0.50 ^a	0.40 ^a	0.52 ^a	0.53 ^a	—
Mean of importance	0.69 ^a	0.85 ^a	0.63 ^a	0.85 ^a	0.80 ^a	0.81 ^a	0.80 ^a	0.59 ^a

Abbreviations: PA, protocol assessment; PP, protocol planning; SR, subject recruitment; ICP, informed consent process; IP, investigational product management; IE, implementation and evaluation; DM, data management; PN, professional nursing role performance.

^a $P < .01$.

^b $P < .05$.

12 sections with 151 items. Subsequently, we performed a field test by administering the Korean CTNQ instrument to 53 CRNs.

Data Analysis

The importance and performance (frequency) data were plotted on a 2-dimensional grid, with importance on the y axis and frequency (performance) on the x axis, using importance-performance analysis of descriptive statistics.²¹ In the pilot test, the reliability (for internal consistency) and convergent validity for the 8 sections of the Korean CTNQ were assessed using Cronbach's α and Spearman correlation analysis.¹⁷ In the field testing to validate the Korean CTNQ, its psychometric properties were examined. The range and distributions of the responses to each item were examined using the ceiling and floor effects. The reliability (for internal consistency) of the 8 sections of the Korean CTNQ was assessed using Cronbach's α and the item-total correlation (scale level). To evaluate the construct validity, convergent validity via scale-level principal-component factor analysis^{22,23} and Spearman correlation analysis were used.

All analyses were performed using SPSS software (version 21, SPSS Inc, Chicago, IL). Differences with a P value of less than .05 were considered statistically significant.

Results

Linguistic Validation (Translation and a Pilot Test)

In the forward translation, all frequency and importance items were translated into Korean without removing or modifying any items. However, 2 questions regarding the "current certification" (in the professional nursing role characteristics) and "What is your primary level of practice?" (in the organizational characteristics) were removed because there is no qualification system for Korean CRNs and most Korean CRNs work without a formal position. In addition, questions regarding the subjects' ethnicity were removed, and the geographic regions in the demographic information were changed to the names of Korean regions. In the cognitive debriefing of the 10 Korean CRNs, the

Cronbach's α values for 8 sections in the Korean CTNQ were 0.97 for frequency and 0.98 for importance, and the convergent validity according to the Spearman correlation coefficients' validity was good (Table 3).

Mean Scores of the Importance and Frequency (Performance) Subscales of the Korean CTNQ

The descriptive mean scores of 8 importance and performance (frequency) subscales of the Korean CTNQ were presented as an importance-performance analysis map. The informed consent process, implementation and evaluation, data management, and investigational product management were the most important and frequent roles (Figure).

Floor Effects and Ceiling Effects

The distributions of the item responses for the Korean CTNQ were mostly appropriate. There were no high proportions for floor effects (the proportion having the minimum score) and ceiling effects (the proportion having the maximum score), with a range of 1.08% to 15.05%, except for the higher ceiling effects for importance in the informed consent process (34.0%) and investigational product management (26.4%) (Table 4).

Reliability

The internal consistency reliability (Cronbach's α) for the frequency scale of the Korean CTNQ was 0.852, compared with 0.899 for the importance scale. The item-total correlation ranged from 0.51 to 0.72 for the frequency scale and from

0.29 to 0.66 for the importance scale. Each scale was internally consistent and acceptable; therefore, the Korean CTNQ seems to be reproducible (Table 4).

Construct Validity via Convergent Validity

Eight sections of the Korean CTNQ were mostly correlated with each other, except for among the professional nursing role performance, informed consent process, and implementation and evaluation. Another exception was the lack of correlation between the informed consent process and protocol planning (Table 3).

Construct Validity via Factor Analysis

By performing scale-level principal-component factor analysis with varimax rotation of the Korean CTNQ, 3 factors with eigenvalues of 1 or higher were identified; these factors accounted for 68.5% of the variance. Sections 1 to 8 of the frequency subscale in the Korean CTNQ were loaded on 1 factor (eigenvalue=2.75, 17.2% of the explained variance), whereas sections 1 to 8 of the importance subscale were loaded on 2 factors, which accounted for 41.6% of the variance in sections 4 to 8 and for 9.7% of the variance in sections 1 to 3. According to the pattern matrix, the factor loadings of the 16 sections were broadly similar, and these seem to comprise the clinical research nursing roles (Table 4).

Discussion

This study was conducted to evaluate the reliability, validity, and applicability of the Korean CTNQ in the Korean culture, and our results indicate that an acceptable distribution of item

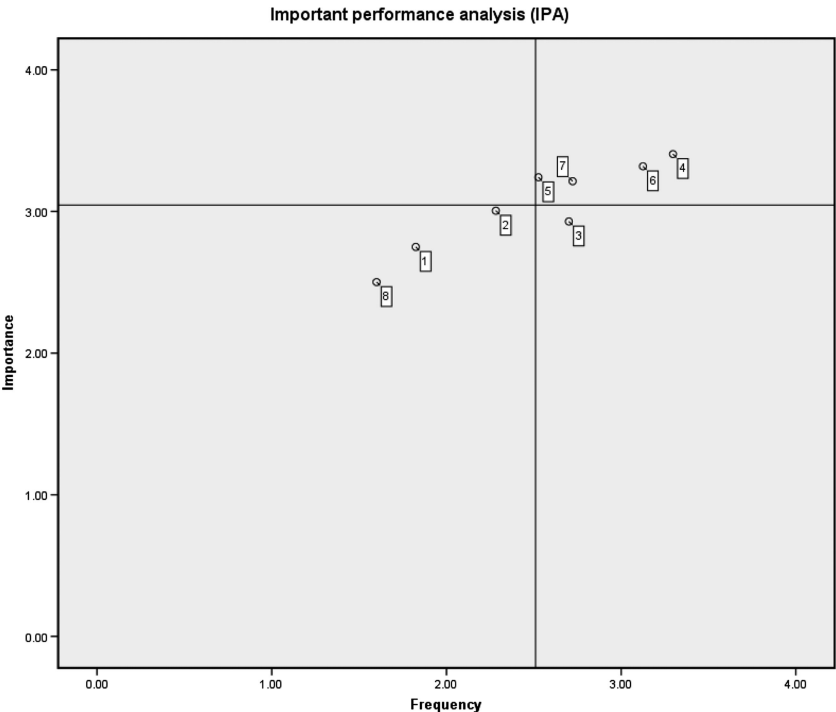


Figure 1 Importance-performance analysis for the frequency and importance subscales in the Korean Clinical Trials Nursing Questionnaire.

Table 4 • Floor and Ceiling Effects, Internal Consistency Reliability, and Factor Loadings of the Frequency and Importance Subscales in the Korean Clinical Trials Nursing Questionnaire (N=53)

Subscale (No. Items)	M±SD (Min-Max)	% Floor Effect	% Ceiling Effect	Cronbach's α	Item-Total Correlation	Factor Loadings ^a		
						Communality	Factor 1	Factor 2
Frequency								
1. PA (16)	1.82±0.78 (0.31–3.75)	1.9	1.9	0.919	0.57	0.68	0.69	
2. PP (14)	2.28±0.76 (0.57–3.93)	1.9	1.9	0.883	0.69	0.74	0.75	
3. SR (15)	2.70±0.54 (1.73–4.00)	3.8	1.9	0.812	0.59	0.74	0.76	
4. ICP (14)	3.30±0.54 (2.00–4.00)	3.8	15.1	0.895	0.64	0.56	0.40	
5. IP (10)	2.53±0.68 (0.90–4.00)	1.9	1.9	0.814	0.51	0.64	0.63	
6. IE (23)	3.12±0.51 (1.87–4.00)	1.9	1.9	0.905	0.73	0.75	0.52	
7. DM (18)	2.72±0.67 (0.67–3.94)	1.9	1.9	0.890	0.64	0.57	0.67	
8. PN (10)	1.60±0.74 (0.20–3.80)	1.9	1.9	0.902	0.56	0.57	0.75	
Mean	2.64±0.46 (1.80–3.79)	1.9	1.9	0.852				
Importance								
1. PA (16)	2.75±0.56 (1.69–3.75)	1.9	1.9	0.868	0.53	0.70		0.76
2. PP (14)	3.01±0.67 (1.64–4.00)	1.9	9.4	0.918	0.53	0.75		0.66
3. SR (15)	2.93±0.54 (2.00–4.00)	5.7	5.7	0.843	0.52	0.66		0.70
4. ICP (14)	3.41±0.65 (1.64–4.00)	1.9	34.0	0.949	0.66	0.85	0.84	
5. IP (10)	3.24±0.75 (0.40–4.00)	1.9	26.4	0.930	0.40	0.70	0.81	
6. IE (23)	3.32±0.52 (1.87–4.00)	1.9	11.3	0.939	0.60	0.78	0.84	
7. DM (18)	3.21±0.65 (1.72–4.00)	1.9	15.1	0.953	0.60	0.81	0.89	
8. PN (10)	2.50±0.74 (1.00–4.00)	1.9	3.8	0.929	0.36	0.44	0.58	
Mean	3.13±0.50 (2.06–4.00)	1.9	10.9	0.899	0.29			
Eigenvalue						6.65	2.75	1.55
% Explained variance						41.6	17.2	9.7

Abbreviations: PA, protocol assessment; PP, protocol planning; SR, subject recruitment; ICP, informed consent process; IP, investigational product management; IE, implementation and evaluation; DM, data management; PN, professional nursing role performance.

^aFactor loadings via principal component factor analysis with varimax rotation (The Kaiser-Meyer-Olkin Measure = 0.810; Bartlett's test of sphericity, $P < .001$).

responses was obtained, with minimal ceiling and floor effects. The reliability and validity of the Korean CTNQ was confirmed by the high internal consistency reliability and the good construct validity.

Both the floor and ceiling effects were also appropriate, and items were chosen to use the full response range, based on a report that floor or ceiling effects of less than 20% are acceptable setting points.²⁴ However, the importance in the informed consent process and investigational product management had higher ceiling effects (34.0% and 26.4%, respectively). This is attributable to the fact that the informed consent process and investigational product management were the most important and frequent roles.

The intraclass correlation coefficient is the most commonly used method for assessing reliability with continuous and ordered categorical data that have more than 4 or 5 response categories for measuring the strength of the agreement between repeated measuring.¹⁷ In this study, the internal consistency reliability for the Korean CTNQ frequency scale was 0.852, compared with 0.899 for the importance scale. However, the Cronbach's α values for the Korean CTNQ were lower than those reported for the original and Italian tools.^{11,13} In addition, a reliability coefficient of 0.9 or higher is recommended if the measurements are to be used for evaluating individual subjects.²⁵ However, for discriminating between groups of subjects, it is usually recommended that reliability should be 0.70 or higher.¹⁷ In the present study, the item-total correlation ranged from 0.51 to 0.72 for the frequency scale and from 0.29 to 0.66 for the importance scale of the Korean CTNQ. Thus, all 8 sections of the Korean CTNQ met the minimal acceptable criterion of an item-total correlation coefficient of 0.20.¹⁷ Therefore, the Korean CTNQ has good intraclass correlations and item-total correlations and is confirmed to be reproducible.

Eight sections of the Korean CTNQ were mostly correlated with each other. Although several correlation coefficients did not meet the minimum acceptable convergent validity criterion (0.40),¹⁷ the results indicate that the Korean CTNQ has good convergent validity. Therefore, these results indicate that the Korean CTNQ is appropriately valid, compared with the original English CTNQ.

Scale-level factor analysis could be performed in the psychometric evaluation because of its statistical usefulness.^{22,23} However, the size of the sample did not permit item-level analyses in this study. Ideally, only 2 factors of the importance and frequency subscales in the Korean CTNQ would be yielded, based on the conceptual model. However, our analysis yielded 3 factors that had eigenvalues of 1 or higher, according to the scale-level factor analysis. One factor that was produced accounted for 17.2% of the variance in the frequency subscale, 2 factors that were produced accounted for 51.3% of the variance in the importance subscale, and the factor loadings were broadly similar. Therefore, despite our analysis yielding 3 factors, our results from the principal component factor analysis of the Korean CTNQ indicate good construct validity.

■ Conclusion

The results of this study support the use of the Korean CTNQ in studies that assess and evaluate the Korean clinical research

nursing roles. We suggest that the validated Korean CTNQ could be applied as a means of establishing general competencies that are required for basic and advanced levels of clinical research practice in a larger, more diverse population of CRNs.

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