RESEARCH ARTICLE

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Development and Psychometric Validation of Patient-Reported Outcome Measures (PROMs BCC-20) for Assessing Comfort during Chemotherapy in Breast Cancer Patients

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Abstract

Objective: The study aims to develop and psychometric validate Patient-Reported Outcomes Measures for Assessing Comfort during Chemotherapy in Breast Cancer Patients (PROMs BCC-20). **Methods:** This study was conducted in two phases: 1) items were developed from the literature review and in-depth interviews, and 2) Exploratory factor analysis (EFA), Confirmatory factor analysis (CFA), and concurrent validity were performed to evaluate construct validity. The participants were cancer stage I-IIIC, adult females, performance status was assessed by Eastern Cooperative Oncology Group (ECOG) score ≤ 2 after receiving the second cycle of adjuvant chemotherapy and selected by purposive sampling method. For each group of EFA and CFA was 250 participants. **Results:** Five hundred breast cancer patients during adjuvant chemotherapy were recruited from three tertiary cancer centers. A succession of EFA using principal axis factoring with Promax rotation revealed four dimensions yielded a seven factors solution, explaining a 60.07 percent variance. CFA contains 20 items with five factors; 1) social function, four items; 2) digestive function, three items; 3) emotional function, six items; 4) environmental function, three items; and 5) sleep quality, four items via maximum likelihood with bootstrapping indicated a good fit model (SRMR = 0.045, RMSEA = 0.040, CFI = 0.947, and TLI = 0.935). The Cronbach's alpha of 0.86 demonstrated strong internal consistency reliability. Pearson's correlation coefficient showed acceptable criterion validity. **Conclusion:** The PROMS BCC-20 provides good psychometric properties and practical patients' direct reports of comfort in breast cancer patients during chemotherapy. The PROMs BCC-20 should be standardized for comfort measurement and tailor-made nursing care to provide patient satisfaction and good nursing outcomes.

Keywords: Patient-Reported Outcomes Measures- psychometric validation- comfort- chemotherapy- breast cancer

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Introduction

The National Cancer Institute of Thailand (NCI) stated that the breast is the organ most affected by cancer among new Thai cancer patients regarding overall updates in the incidence year 2019. From the data report, early-stage (stage I-IIA) and locally advanced stage (stage IIB-IIIC) cancers are 81.88% prevalent. The metastatic stage (stage IV) is only 18.12% dominant (National Cancer Institute, 2019).

Physicians can diagnose the cancer stage by a pathology result. Standard breast cancer treatment at stage I-IIIC can undergo treatment surgery and follow adjuvant treatment such as chemotherapy, targeted therapy, radiation therapy, or hormonal therapy. Unlike stage IV, patients are unresectable and need more treatment since cancer has now spread to other organs (National Comprehensive Cancer Network, 2021). Breast cancer patients often experience various symptoms and considerable discomfort during adjuvant chemotherapy. The physical discomfort symptoms included nausea, vomiting, pain, shortness of breath, memory problems, loss of appetite, taste change, arthralgias, peripheral neuropathy, insomnia, constipation, abdominal discomfort, disturbed sleep, distress/upset, drowsiness, sadness, fatigue, and depressive mood (Ahadzadeh and Sharif, 2018; Crouch et al., 2022; Dewan et al., 2022; Phongnopakoon et al., 2023). The suffering from the treatment side effects affected their mental state and quality of life (Deng and Chan, 2017; Takahashi et al., 2022). During chemotherapy, relief from the symptom discomfort of breast cancer patients increases the possibility of the patient experiencing safety during treatment (Bergström et al., 2018). The impact of unsatisfied needs of patients affected individuals' physical and psychological difficulties. The theory of comfort consists of these four components: physical, psycho-spiritual, socio-cultural, and environmental, starting with patient comfort needs and support needs

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from nursing intervention (Kolcaba, 1991).

However, the existing PROMs currently used are generic measures also in Thai people. The patient group involves general comfort, end-of-life, hospice, and people receiving healing touch massage, pediatric care, surgery (preoperative), and care in psychiatry, urology and gynecology, acute care, and radiation therapy. It did not specify comfort in breast cancer patients during chemotherapy (Pinto et al., 2017). The new instruments should be developed to assess comfort during chemotherapy in Thai breast cancer patients, especially the physical part. Thus, the specific instrument utilization is more sensitive in assessing comfort in Thai breast cancer during chemotherapy.

Comfort measurement is necessary for nursing interventions to address patient comfort levels and thus improve the chances of simultaneously understanding the patient's needs. Patient-reported outcome measures (PROMs) in clinical care are defined as any report of their health status without interpreting their condition (Biber et al., 2018; Yuan, 2018). However, some issues are most meaningful from the patient's perspective, and the patient's self-reports reflect the best way to ensure that patients receive optimal care quality (Gilbert et al., 2015; Camuso et al., 2016; Catt et al., 2017). Thus, holistic nursing care and nurse empathy consist of interpreting and identifying patient needs by conducting comprehensive patient reports to increase treatment efficacy and safety (Wei et al., 2017; Barilaro et al., 2019).

This study had two phases; one of the questionnaires was generated, and the other evaluation quality of PROMs was based on psychometrics validation. This study aims to develop and test the psychometric properties of the PROMs for assessing comfort in breast cancer patients during chemotherapy, where a highly comprehensive area and sensitive to nursing care.

Materials and Methods

Sample and data collection

The data were collected between September 2020 and May 2021 at three ambulatory chemotherapy centers representing government and private settings. All participants were Thai patients diagnosed with breast cancer after receiving the second cycle of adjuvant chemotherapy. The participants were stage I-IIIC adult females with an ECOG score ≤ 2 after receiving the second cycle of adjuvant chemotherapy. Thai breast cancer patients with uncontrolled comorbid diseases and recurrences were excluded. The participants were selected using the purposive sampling method. After approval from IRB, interviews of the participants commenced. The researcher gave introductions and explained the interview objectives, the participants consented and signed their informed consent forms to participate in the project. Five hundred participants were recruited for psychometrics properties testing. This was based on Burn and Grove's recommendation of 5-10 times the number of items (Burn and Grove, 2001). These participants were randomly split into two groups. The first set of data from 250 participants was exposed to EFA, while the second set from 250 participants used CFA to confirm the construction of the final PROMs BCC-20.

Phase I

The phase I data comprised interviews of fifteen breast cancer patients during chemotherapy with semi-structured questionnaires, which three nurses who were experts in phenomenology approved. The inductive method (codes extracted from semi-structured personal interviews) and deductive (codes extracted from the literature review) will be used for data collection (Nikpour et al., 2018). The trustworthiness strategies ensured the validity and reliability of the data. Guba's constructs correspond to the criteria of credibility, transferability, dependability, and confirmability (Guba, 1981). As a result, the interviews and literature review were performed to clarify the concept and dimensions of comfort. After finding items and grouping the relevant items, the comfort remained 21 items. Items grouped into four components were composed of physical comfort, eight items; psycho-spiritual comfort, five items; socio-cultural comfort, four items; and environmental comfort, four items. We might use it to generate the primary item pool for phase II.

Phase II

This phase focused on developing and assessing the psychometric properties of the PROMs, their face validity, content validity, construct validity, and reliability testing. A cross-sectional design was used to develop and measure the validity and reliability of the questionnaire. PROMs development consisted of sequence steps complying with the Ten-steps of developing the instrument (Srisatidnarakul, 2012). This study used EFA, followed by CFA, and concurrent validation with the relative gold standard of measurement.

The results are from phase I; the questionnaire items were obtained. The first draft of the PROMs was subdivided into the following two sections: section 1 contained the questionnaire requesting primary data from the participants, and Section 2 contained a questionnaire with four components and 21 comfort items. The items will be scored on a Likert-type plus an analytic rubric combined with a scoring scale on interpretations for participants to rank opinions on a scale from 1 to 5 (Discomfort to the most comfort).

Content Validity and Face Validity

Content validity was established from the opinions of a panel of experts. In this regard, four experts were chosen due to their expertise in comfort during chemotherapy matter (1) psychologist, psychosocial expertise, (2) palliative doctor, socio-cultural expertise, (3) oncology nurse in a chemotherapy center, and (4) oncologist physician. This study had an I-CVI of .90, and an S-CVI of .98, indicating that it is acceptable (Shi et al., 2012). Furthermore, a face validity assessment will be done, all items were contextually relevant, and no item was deleted for details of clarification, simplicity, and no ambiguity. Therefore, no modification was recommended (Nikpour et al., 2018).

Initial Reliability and Item Analysis

The second draft of the PROMs was assessed with a small sample group of 30 Thai breast cancer patients. The reliability analyses assessed the values of each component, corrected the item-total correlation, and used Cronbach's Alpha Coefficient. A good assessment form should have an inter-item correlation ranging from .30 -.70 and not exceed 50% of the total score (Srisatidnarakul, 2012). The Cronbach alpha for the scale was 0.89, indicating good reliability. Item analysis was also evaluated with an inter-item correlation ranging from .30 -.70, accounting for 50.2% of all values. These results indicated that the questionnaire had a good inter-item correlation in particular areas. This procedure resulted in the retention of four main components comprising 23 items: physical comfort with ten items, emotional-mental comfort with five items, socio-cultural comfort with four items, and environmental comfort with four items. Therefore, the third draft of the PROMs was developed with 23 items.

Conduct a Validity Verification Procedure

The analysis aimed to explore and confirm the post-pilot test of the PROMs' psychometric properties. This study used EFA and CFA to confirm the measurement structure of the PROMs BCC-20 and concurrent validation with the relative gold standard of measurement. The Statistical Package for the Social Sciences (SPSS) program was used for the EFA, and M plus statistical program was used for the CFA.

Results

Participant's Characteristics in the Factor Analysis Process

Table 1 shows that the patients who had fully completed the assessment (n = 500) had already been tested for data attrition and error. The most common stage was stage 3 (46.4%). The most frequent type of chemotherapy was Adriamycin-based (42.6%). ECOG score of most patients (39.8%) yielded a score of 0. The cycles of chemotherapy were the 4th, 2nd, and 3rd, representing 24, 20.4, and 19.8% of the patients, respectively. Most pre-chemotherapy treatments, 57.8%, involved mastectomy. Most patients were aged 51-60 (45.4%) and married (51.8%). Nearly all patients (93.6%) were Buddhists in terms of religion. Most caregivers during chemotherapy were sons/daughters (37 %), and the most frequent healthcare treatment coverage was provided under the Universal Coverage scheme (48.6%). The study sample (n = 500) was randomly split into two datasets of equal size, an "EFA sample" (n = 250) and a "CFA sample" (n = 250).

Exploratory Factor Analysis (EFA)

Before conducting the EFA, assumptions of the EFA statistics were examined, including normality, multicollinearity, Bartlett's test of sphericity, and The Kaiser-Meyer-Olkin value (KMO) measured of Sampling adequacy. The 23x23 correlation matrix of the comfort items were subjected to a principal-axis factoring to identify latent factors underlying the comfort of breast cancer patients during chemotherapy. The results showed that the data were appropriate for using the factor-analysis technique at a high level (Srisatidnarakul, 2012). (Bartlett's test = 1500.589, $p < 0.05$, KMO = 0.792) Finally, the commonalities were all above .30, indicating that each item shared some common variance with other items, indicating that proceeding with the EFA on this data set was appropriate. The Kaiser-Guttman rule (eigenvalue more significant than one) and Cattell's Scree plot indicated seven factors for the PROMs BCC-20. EFA on the 23 items was analyzed using Principal component analysis with Promax rotation to determine the underlying constructs of each section. The seven factors together explained 60.07% of the total variance in the scale, where the optimal value should be more excellent than 60% (Hair et al., 2010).

After examination of the items associated with each factor, the factors were labeled Component 1 as the social function, component 2 as the digestive function, component 3 as the emotional function, component 4 as environmental quality, component 5 as sleep quality, component 6 as pain and neuropathy and component 7 as a family relationship. Table 2 presents a factor loading of items in 7 components.

Confirmatory Factor Analysis (CFA)

In order to study the replicability of the seven-factor solution generated by EFA, CFA was conducted on the second set of data (N = 250), analyzing the items and latent constructs for the Comfort Inventory. Seven factors and 23 items were analyzed in the second-order analysis. The CFA process eliminated fatigue (P4), digestion (P6), and weather during chemotherapy (EV1) because of items resulting from low-factor loadings. An excellent model fit was indicated by a standardized root-mean-squared residual (SRMR) ≤ 0.08, a root-mean-square error of approximation (RMSEA) ≤ 0.08, and a comparative fit index (CFI) ≥ 0.92. For the RMSEA value, a 90% confidence interval (CI) was included (Hair et al., 2010). The study result of the CFA revealed that the model fits the data ($\chi 2 = 217.764$, RMSEA = 0.040, SRMR= 0.045, CFI = 0.947, and Tucker-Lewis index [TLI] = 0.935). Furthermore, the findings indicated that all 20 items were the model fits well. Therefore, the instrument was proven valid for measuring the constructs.

The final draft of the PROMs BCC-20 had five main components:1) social function, four items which included contact and activities with peer groups, work with coworkers, the performance of family roles and numbness in the peripherals; 2) digestive function, three items; which included constipation, nausea and vomiting and eating numbness in the peripherals.; 3) emotional function, six items which included stress caused by dark marks in the nails and blood vessels following the chemotherapy line, stress caused by hair loss, encouragement for chemotherapy, sexual relationships, emotional regulation, and concern and worry about family members or loved ones; 4) environmental function, three items which included ease of sleep, waking up during sleep, daily-life activities and bone pain in the limbs; and 5) sleep quality, four items which included light or noise during chemotherapy, the comfort of the bed or

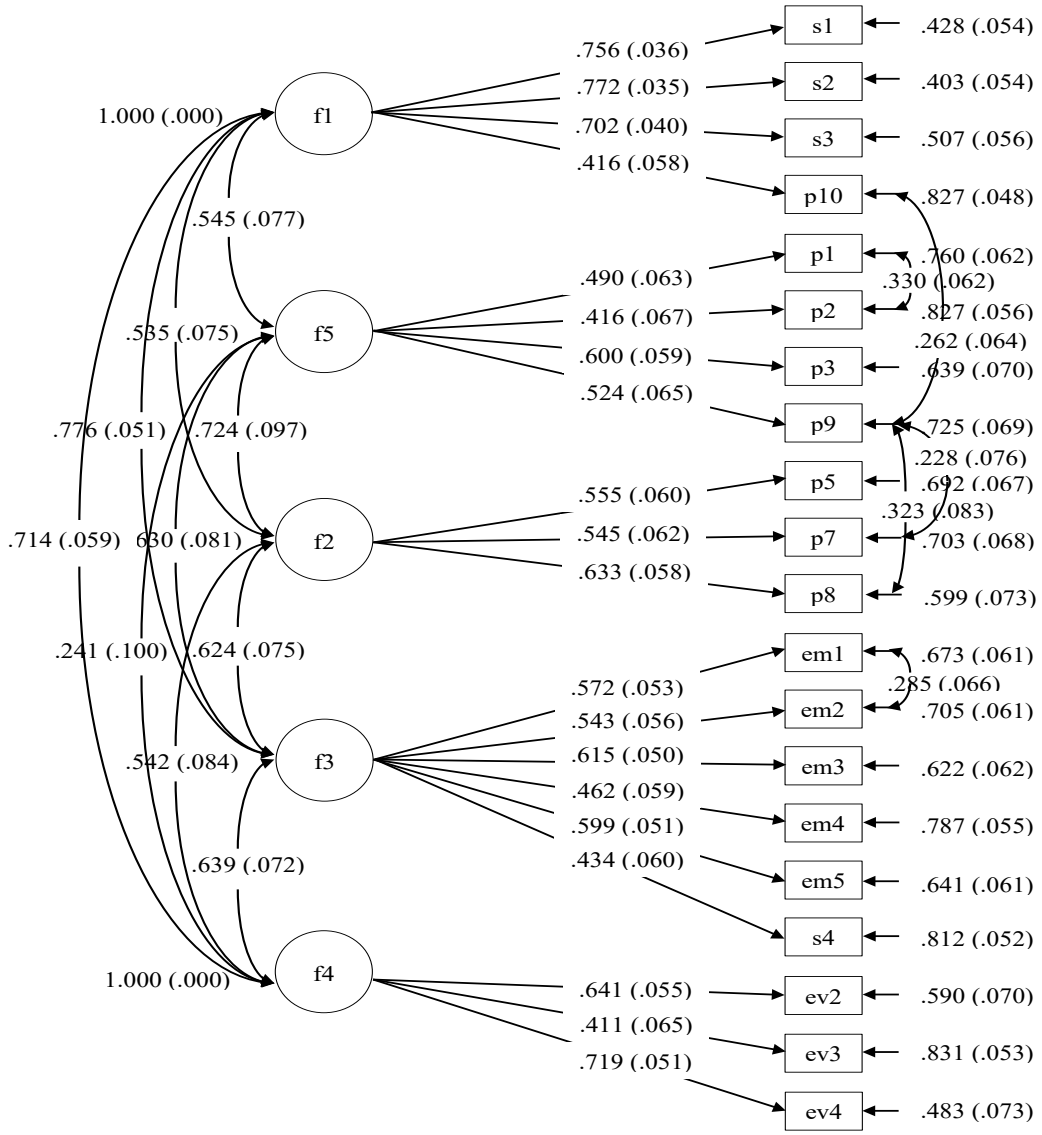

Figure 1. CFA Results for the Five-Component PROMs BCC-20 (n = 250). Note: All abbreviations have full terms in Table 2

chair occupied by the patient during chemotherapy, and feelings of the patients about the hygienic environment at home who had low white-blood-cell counts, shown in Figure 1. In addition, Cronbach's alpha coefficient was 0.844, a reliability test for the last version of the PROMs.

Concurrent Validity

Concurrent-related validity indicates the agreement between two assessments. One assessment is new, while the other is well-established and has already been proven valid. Pearson's correlation testing evaluated the concurrent validity between PROMs BCC-20 and EORTC QLQ-C30, Version 3. The European Organization for Research and Treatment of Cancer developed the questionnaire to measure QoL, especially in cancer patients. The sample size was tested on 90 participants and was calculated by G*power (Cohen, 2013).

The result (Table 3) showed a strong association between the two instruments for symptom scales (r = 0.715). A moderate association between emotional function (r = 0.465) and social function (r =0.404). Moreover, all the items showed a strong association (r = 0.701).

Internal Consistency

Internal consistency reliability estimates were computed using Cronbach's alpha coefficients for each factor. The Cronbach's alpha coefficient was 0.75 for the social function, 0.70 for emotional function, 0.63 for environmental, 0.62 for sleep quality, and 0.62 for digestive function, respectively. In all components, they were 0.84.

Development of a Scoring System

The PROMs BCC-20 items were scored on a five-point rubric-score type scale, ranging between 1 to 5. After determining the weight of each item, the standard 0-100 scoring scale was used. The raw scores of the questionnaire were converted to 0-100 points using the linear transformation equation, as depicted. The patient

Table 1. Characteristics of Participants in the Factor Analysis Process (n = 500)

Participant characteristics		Breast cancer patients	
		Number	Percentage
Cancer Stage	Stage I	53	10.6
	Stage II	215	43
	Stage III	232	46.4
Type of Chemotherapy	Adriamycin-based	213	42.6
	Paclitaxel-based	202	40.4
	Docetaxel-based	63	12.6
	Other	22	4.4
Performance Status (ECOG score)	Score 0	199	39.8
	Score 1	183	36.6
	Score 2	118	23.6
Number of Chemotherapy Cycles	Cycle 2	102	20.4
	Cycle 3	99	19.8
	Cycle 4	120	24
	Cycle 5	64	12.8
	Cycle 6	48	9.6
	Cycle 7	22	4.4
	Cycle 8	42	8.4
	Cycle 9 -Cycle 12	3	0.6
Pre-Chemotherapy Treatment	Mastectomy surgery	289	57.8
	Neoadjuvant -chemotherapy	130	26
	BCS	70	14
	Reconstruction surgery	11	2.2
Age	18-30 years	24	4.8
	31-40 years	54	10.8
	41-50 years	150	30
	51-60 years	227	45.4
	61-68 years	45	9
Marital Status	Married	259	51.8
	Single	135	27
	Widowed	50	10
	Divorced	37	7.4
	Separated	19	3.8
Religion	Buddhist	468	93.6
	Christian	14	2.8
	Muslim	13	2.6
	Sikh	4	0.8
	Unknown	1	0.2
Caregiver	Son/daughter	185	37
	Brother/sister	85	17
	Spouse/wife	78	15.6
	Father/mother	70	14
	None	46	9.2
Caregiver	Closed parents	23	4.6
	The caregiver is a non-family member	8	1.6
	Other	5	1
Healthcare treatment coverage	Universal Coverage scheme	243	48.6
	Social security scheme	113	22.6
	Government officer	75	15

Table 1. Continued

Participant characteristics		Breast cancer patients	
		Number	Percentage
Healthcare treatment coverage	Self-pay Employee Insurance	34	6.8
	Insurance	18	3.6
	Company	17	3.4

groups can be used scores for comparison several times for measured outcomes.

One can report the raw scores in addition to the transformed scores. For example, knowing the proportion of patients exhibiting the "slightest" or "highest" symptoms may be clinically relevant. The raw score also applies to nursing care when the individual responses by item are fascinating.

Discussion

This research aimed to develop and validate PROMs BCC-20. Phase I; revealed Thai breast cancer patients' comfort experiences, needs, and feelings during chemotherapy findings, the themes, and items. Phase II for developing the PROMs was validated content through the qualified expert's judgment. The component of PROMs was improved since some of the experts, in submitting their comments, had recommended changing from the psycho-

Table 2. Factor Loading of Items in 7 Components

Item	Comfort items	Factor						
		1	2	3	4	5	6	7
Social function								
17	(S3) Performance of family roles	0.832						
18	(S2) Work with coworkers	0.795						
16	(S1) Contact and activities with peer groups	0.689						
3	(P3) Daily life activities	0.564						
Digestive function								
8	(P8) Eating		0.732					
5	(P7) Nausea & vomiting		0.698					
6	(P6) Digestion		0.619					
7	(P5) Constipation		0.616					
4	(P4) Fatigue		0.381					
Emotional function								
12	(EM2) Stress caused by hair loss			0.836				
11	(EM1) Stress caused by dark marks in the nails and blood vessels following chemotherapy line			0.734				
15	(EM5) Emotional regulation			0.564				
13	(EM3) Encouragement for chemotherapy			0.558				
Environmental quality								
22	(EV3) The comfort of a bed or chair during chemotherapy				0.79			
20	(EV1) Weather during chemotherapy				0.686			
21	(EV2) Light or noise during chemotherapy				0.63			
23	(EV4) Feelings about the hygienic environment at home with low WBCs				0.574			
Sleep quality								
2	(P2) Waking up during sleep					0.865		
1	(P1) Ease of sleep					0.751		
Pain and neuropathy								
9	(P9) Bone pain in the limbs						0.747	
10	(P10) Numbness in the peripherals						0.742	
Family relationship								
14	(EM4) Sexual relationship							0.692
19	(S4) Concern and worry about family members or loved ones							0.654

Table 3 Pearson's correlation analysis results

Component	Symptom scales EORTC	Emotional function EORTC	Social function EORTC	All items EORTC
Symptom scales	0.715**			
Emotional function	0.551**	0.465**		
Social function	0.429**	0.375**	0.404**	
All items	0.734**	0.492**	0.311**	0.701**

** Correlation is significant at the .01 level (2-tailed).

spiritual component to the emotional-mental component and added two items to 23 items. The descriptive and clinical characteristics of the participants are consistent with other studies exploring the comfort experiences of breast cancer patients during chemotherapy (Coolbrandt et al., 2016; Pearce et al., 2017; Wei et al., 2017). The existing comfort instruments that rely upon Comfort theory (Kolcaba, 1991) were grounded studies conducted on palliative, and end-of-life cancer patients, mentioning the psycho-spiritual component (Kolcaba, 1991; Pinto et al., 2017; Nuraini et al., 2018). The differential findings were found in this study with non-metastatic cancer patients; they mentioned the emotional function rather than the spiritual one. Nevertheless, the results indicated that the overall internal consistency of the PROMs is quite good.

The psychometric properties testing for construct validation with EFA were significant above seven components and 23 items, and the structural confirmation with CFA revealed that the model fit, the data with five components, and 20 items of the PROMs were on the last version. Our questionnaire has strong internal consistency reliability, and most items included are strongly parallel with hypothesized constructs. The PROMs BCC-20 was designed to be a self-reported questionnaire that is easy to use and will allow researchers and practitioners to obtain a better perception of comfort assessment in Thai breast cancer during chemotherapy.

The items in this questionnaire in the part of digestive function component are not different from several studies. Eating, nausea and vomiting, and constipation were the most frequently occurring symptoms during chemotherapy (Ward Sullivan et al., 2018; Singh et al., 2022). Chemotherapy-induced nausea and vomiting (CINV) are associated with a significant deterioration in QoL, affecting the comfort levels of patients experiencing this symptom (Navari, 2014). Body image is also a critical concern in Thai female patients. Understanding the body concept reveals the subject's psychological component. Signs of anxiety, concentration disturbance, and depression have expressed the emotional function. The comforting environment patients requested were a bed, chair, and relaxing environment during chemotherapy because they sensed increased simultaneous antagonistic muscle activation (Kneis et al., 2016). Moreover, drug-induced immune thrombocytopenia (DITP) is a severe complication during chemotherapy. Patients are often concerned about hygienic environments (Kam & Alexander, 2014), especially the timing of this study in the COVID-19 pandemic.

The steps of PROMs development relied on the standard of the International Society for Quality-of-Life Research (ISOQOL) to solicit input on PROMs of the conceptual and measurement model, which would include evidence for reliability, validity (content and construct validity) and interpretability of scores; quality translation; and an acceptable patient burden (Reeve et al., 2013). The time spent completing the questionnaires was only 15-20 minutes, which was not a burden to the patients.

This is the first PROMs developed to assess comfort in Thai breast cancer patients during adjuvant chemotherapy. Several items found in this study correspond with a trend of breast-cancer prevalence at a youthful age that differs from the past study. At this age group, women continue to work and have social connections with peer groups and active roles in the family; this component was a significant issue in comfort elevating (Tuncer and Yucel, 2014).

Based on results, PROMs work well when implementing patient education, nursing services, and patient-management plans. The impact of the PROMs feedback on patient experiences is that the feedback received can be used to identify and prioritize nursing care for patients' outcomes after the intervention. PROMs focus on the patient's perception to communicate between patients and healthcare providers, monitor nursing care and provide patient intervention. The nursing team needs to communicate effectively to prioritize the severity of adverse events from cancer treatment and improve their follow-up nursing care. Better management standards are necessary because quantifying care quality is often complicated and challenging. The result could increase patient-care values. According to the findings, the PROMs BCC-20 were developed based on comfort, including social function, digestive function, emotional function, environmental, and sleep quality. PROMs are critical in assessing patients' comfort experience. The study found that PROM BCC-20 demonstrated acceptable psychometric properties to measure comfort in Thai breast cancer patients during adjuvant chemotherapy. Therefore, it can help nurses identify patients' comfort levels during chemotherapy with specificity for needs support. PROMs can evaluate the quality of care compared to before and after nursing intervention for care quality improvement. Integrating the PROMs BCC-20 into practice simplifies and improves access to healthcare providers for their patients, creating an environment where patients can feel more comfortable disclosing detailed reports about their current states of comfort to the care team.

Limitations of the Study

This study was performed with Thai participants, specifically women with stage-I-IIIC breast cancer

receiving adjuvant chemotherapy. The PROMs BCC-20 should be extensively assessed with cancer patients during chemotherapy for the several types of cancer and different biographic characteristics. Standardized comforts can be created and appropriately used for other cancer patients during chemotherapy.

Author Contribution Statement

Boonjai Srisatidnarakul: Conceptualization, methodology, investigation, data curation, supervision, original draft, writing review & editing, and final approval; Paranee Phongnopakoon: Conceptualization, methodology, investigation, data curation, formal analysis, writing an original draft, and writing review & editing; Yu-Yun Hsu: Conceptualization, writing review & editing, and final approval.

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Ethical Declaration

This study was approved by the ethics committee of Thammasat University, No. 3 (No. 093/2563 on 20/09/2020), Bangkok Hospital (No.BHQ-IRB-2020-07-21 on 02/09/2020), National Cancer Institute, Thailand (No.020_2020T_OUT662 in 03/08/2020), Rajavithi hospital (No.64146 in 19/06/2021). Data was collected after permission was obtained from the director of each hospital. The researcher selected the volunteer participants and explained this to them. Written informed consent was obtained from them before data collection was conducted.

Conflict of Interest

The authors declare that no conflict of interest exists.

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