

Validation of the Modified Thai Cancer Survivor's Unmet Needs (T-CaSUN) for Cholangiocarcinoma Patients

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Abstract

Background: Cancer survivors frequently experience of unmet demands that are linked to psychological illness, anxiety, and quality of life. Cholangiocarcinoma (CCA) survivors, on the other hand, still lack of validated tool to assess their particular requirements. The aims of this study were to adjust the Cancer Survivors' Unmet Need Scale (CaSUN) to a shorter form and to examine its psychometric scale-specific features for the Thai CCA survivors. **Methods:** This cross-sectional study recruited 231 CCA survivors and randomly split them into 2 groups (group 1, n=115, and group 2, n=116). Firstly, we modified and translated the CaSUN to ensure Thai cultural adaptation. Secondly, we used the statistical methods to reduce some items, then an exploratory factor analysis (EFA) using group 1 to explore the factor structure of the T-CaSUN was done. Finally, a confirmatory factor analysis (CFA) using group 2 was conducted to confirm the modified structure suggested by the EFA and to test for the construct validity of the T-CaSUN. **Results:** Participants consisted of 231 CCA survivors. EFA and CFA organized the four components construct T-CaSUN, which included intensive care, information, relationship, and medical care. The T-CaSUN's internal reliability was good (Cronbach's alpha was 0.75). Furthermore, construct validity was linked to bodily consequences, anxiety and depression, support care needs, stage of cancer, and age. For assessing unmet needs among CCA survivors in Thailand, the T-CaSUN exhibited acceptable reliability and validity. **Conclusion:** The T-CaSUN demonstrated acceptable reliability and validity for assessing unmet needs among CCA caregivers in Thailand. This short form measurement can assist healthcare practitioners in providing successful individualized care by focusing on the particular requirements of these survivors.

Keywords: CCA survivors- Thai- psychometric validation- supportive care- unmet need

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Introduction

Cholangiocarcinoma (CCA), a serious and persistent public health problem with the highest incidence in Northeastern Thailand, was responsible for a high rate of morbidity and mortality (Treeprasertsuk et al., 2017). According to the World Health Organization's (WHO) International Agency for Research on Cancer [IARC] report from 2020, there were 905,677 new CCA cases globally with 830,180 of them dying (Sung et al., 2021). Although an advancement of medical screenings a long with treatment strategies impact on the increasing number of CCA survivors (Pongthavornkamol et al., 2019), these patients may suffer from negative effects of the pathology and CCA treatment strategies that impair their physical, psychological and unmet need (Wohlleber et al., 2021). In addition, after completion of cancer treatments, a number of cancer survivors also describe their need related to their illness in various features (Pongthavornkamol et al., 2019).

In general, most cancer survivors have at least one unmet demand, which is strongly associated to their psychological morbidity, anxiety, and quality of life (QOL) (Wang et al., 2018). To challenge with these problems, the Institute of Medicine (2006) recommended the survivorship care plans to evaluate the supportive care needs from a patient's views that is crucial for the patient centered supportive care development. Thus, these cancer patients also have a broad range of supportive care needs from coping with both the cancer's effects and the psychological and psychosocial statement effect, including depression, anxiety, and feelings of isolation (Wang et al., 2018). As a result, it is crucial for oncology healthcare practitioners to effectively identify and treat cancer patients' unmet care needs in order to improve their QOL.

A self report questionnaire, the Cancer Survivors' Unmet Needs Measure (CaSUN), definitely developed for evaluation the cancer survivors' supportive care needs comprising with five components including

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existential survivorship, comprehensive cancer care, QOL, information, and relations (Hodgkinson et al., 2007). Therefore, to understand these unmet needs may assist in the development of beneficial interventions for CCA survivors. Nowadays, this instrument has not only been extensively recognized, adapted, and interpreted for use in the healthcare settings in various nations, including Dutch (Hodgkinson et al., 2007), Spanish (Tyson et al., 2018), Chinese (Li et al., 2020), and Japanese (Komatsu et al., 2020), but it has also been demonstrated to be a rational and trustworthy evaluation tool. In Thailand, the original version of this tool was being applied for evaluating unmet needs among various cancer survivors such as breast cancer and lung cancer by Pongthavornkamol et al (Pongthavornkamol et al., 2019), yet for CCA survivors remain lack of validated unmet scales that limit the comparability of the finding. In addition, earlier research comparing unmet need to various types of malignancies has found that the relative impact of each component of unmet need varies. These differences could be due to differences in the population, healthcare system, or study design. As a result, the original version of the CaSUN questionnaire was used differently in different investigations, as indicated by the incompatible items and natural factors generated (Keeman et al., 2018; Tyson et al., 2018; Komatsu et al., 2020; Li et al., 2020), and several methodology flaws were discovered in many earlier CaSUN validation research. Similarly, the methodological approaches used in numerous investigations were either insufficient or inappropriate; for example, exploratory factor analysis (EFA) analysis with principal component and orthogonal rotation suggested that the underlying structures of CaSUN are both uncorrelated and unlikely to be correct, leading to the belief that the underlying structures of CaSUN are both uncorrelated and unlikely to be correct. (Hodgkinson et al., 2007). Furthermore, while EFA by itself may not provide sufficient proof of idea validity, principal component analysis is commonly recognized as a poor statistical approach for determining the structure of components. (Hodgkinson et al., 2007). As a result, the growing number of CCA survivors in Thailand necessitates the development of a validated needs assessment tool to investigate their unmet needs. Among this study, we look at the CaSUN's construct and criterion validity in Thai CCA survivors.

Materials and Methods

Study design and population

This two-phase cross-sectional study aim to evaluated psychometric features of the Thai Cancer Survivor's Unmet Needs (T-CaSUN) for CCA survivors of all stages at Srinagarind Hospital, Khon Kaen provinces, Thailand from February 2021 to April 2021. The inclusion criteria 1 were CCA survivors aged 18 and above diagnosed with CCA by board-certified clinicians, could read Thai, and were willing to participate in this study. Therefore, this cross-sectional study included 231 CCA survivors.

Step 1: Instrument Translation and Face Validity; Cancer Survivor's Unmet Needs

The original CaSUN is a 42-item self-administered

scale. It was created to assess patients' needs in six areas: existential survivorships, comprehensive cancer care, knowledge, QOL, and relationships (Hodgkinson et al., 2007). The English version CaSUN items were translated to Thai utilizing Brislin's forward and backward translation technique throughout the study's questionnaire construction (Brislin, 1970). Four English-Thai multilingual translators were discovered, and two were utilized to forward translate the CaSUN instrument into Thai, with the remaining interpreters translated it back from Thai to English. Then, other two native English speakers compared the original and back-translated versions of CaSUN. Finally, the T-CaSUN was tested in a pilot group of 20 Thai CCA patients to evaluate how well it translated and how easy it was to use the test. To verify understanding, the participants were requested to read and listen to all items.

Step 2: Evaluating the Psychometric Properties of the T-CaSUN

The data was collected with the agreement of the hospital's authorized person, and all subjects supplied signed informed consent. Participants were gathered until a participant self-report was used to finish the data collection.

Study instruments

The Thai version of Cancer Survivor's Unmet Needs (T-CaSUN) for CCA survivors were translated version of the CaSUN (Hodgkinson et al., 2007). This instrument is consisted of 35 items. All items are rated on participants answer whether the needs described by the items are not applicable, met, or unmet. If an unmet need is reported, the intensity of the need is then rated as weak (score 1), moderate (score 2), or strong (score 3), the total score was the sum of all need items, with higher scores indicating greater unmet needs.

The Thai version of the Memorial Symptom Assessment Scale-Short Form (MSAS-SF) is a 32-item inventory rated on a 5-point Likert-type scale. Its purpose is to determine the frequency, severity, and distress associated with; 32 separate, multidimensional symptoms experienced by patients (Chang et al., 2000). The MSAS-SF has been used with a wide range of illnesses and it's suitable for either clinical or research settings (Menezes et al, 2017; Webber and Davies, 2011; Wookey and McKean, 2016). Higher scores indicate more frequent occurrences, severity, and suffering. If a symptom is not present, each dimension receives a value of 0 and the symptom receives a score of 0. If a symptom exists, the symptom score is the sum of its dimensions.

The Hospital Anxiety and Depression Scale (HADs) was used to assess a self-reported symptoms of anxiety and depression (Zigmond and Snaith, 1983). The HADs consists of 14 items including 7 items for anxiety and 7 items for depression. It evaluated the severity of symptoms throughout the previous week. The questions were rated on a 4-point Likert scale, with total scores ranging from 0 to 21 for both anxiety and sadness. A score of more than eight indicates that anxiety and sadness are being considered.

In addition, the questionnaire included questions relating to socio-demographics including age, gender,

education level, marital status, comorbidity, cancer stage at diagnosis, and metastasis.

Sample size

The sample size was calculated using the formula "sample size = number of items X number of participants," which is a regularly used formula in survey development research. The sample size for each survey item should be between 5 and 10 participants, according to this calculation (Suresh et al., 2012). As a result, 231 CCA survivors were included in this cross-sectional study. The exploratory and confirmatory factor analyses were conducted on a random split of the subjects into two group samples (group 1, n= 115, and group 2, n= 116 to avoid model overfitting.

Data analysis

Demographic data of the participants were summarized using descriptive statistics with means and standard deviation for continuous variables and counts and percentages, for categorical data.

For the T- CaSUN measurement model, Parallel analysis (based on principle component analysis) was conducted to discover the number of components in EFA using sample group 1, and the factor's structure was then studied using principal axis factoring. The remaining held out participants were subjected to a CFA based on the principal axis factoring results. The measurement model was fitted by a maximum likelihood estimate CFA, and the cumulative fit index (CFI), the adjusted goodness of fit index (AGFI), the root-mean-square error of approximation (RMSEA), and the Tucker-Lewis index were used to assess model fit (TLI) (Hu and Bentler, 1999), GFI (Shevlin and Miles, 1998), and AGFI p-value >0.9 (Byrne, 2011) and RMSEA p-value <0.08 (Browne and Cudeck, 1992) was used to represent adequate model fit. The χ^2 was also reported, even it is a poor indicator of measurement model fit, but included in this study for the convention reason. The Bartlett's test of sphericity and the Kaiser-Meyer-Olkin (KMO) measure of the sampling adequacy were created along with the CFA to provide the further evidence of construct validity (Kaiser, 1974).

Internal consistency reliability was evaluated using Cronbach's alpha, and an acceptable reliability was considered to be alpha > 0.7 for all the subscales (Kline, 2000). Convergent validity was conducted using Pearson correlation coefficient to examine the association between the domains of the T-CaSUN and other psychological variables such as the MSAS-SF, the T-SCNS-P&C, and the HADs scale. In addition, discriminant validity was used to investigate the link between the T-CaSUN domains with other factors such as patient characteristics, stage of cancer to test the construct validity of T- CaSUN.

Ethical considerations

This research was approved by the research ethics committee of Khon Kaen University, Thailand (HE631628). Eligible participants were approached by nurses at their regular medical appointments or the study researcher at patient advocacy group meetings. After brief explaining the overview of the study protocol, we obtained

the written informed consent from all participants.

Results

Demographic Characteristics of Participants

The questionnaire was completed by 231 CCA patients (with a response rate of 98%), age ranging from 46 to 95 years old (\bar{x} =66.85, S.D. =8.65) more than half of the participants (66.7%) in the sample were men. (Table 1)

Construct validity

The Thai version of Cancer Survivor's Unmet Needs (T-CaSUN) for CCA survivors were translated version of the CaSUN (Hodgkinson et al., 2007). This instrument is consisted of 20 items and distributed across 4 factors as follows: Intensive care (9 items), information (3 items), relationship (3 items), and medical care (5 items).

After randomizing the participants into two groups (115 patients for EFA, and 116 patients for CFA), parallel analysis was done and an appropriate single factor structure was confirmed. Then, the principal axis factoring was conducted to explore the factor structure and the resulting loadings are demonstrated in Table 2. An unweighted least square CFA was conducted to fit the T-CaSUN measuring model which consisted of 20

Table 1. Characteristics of the Participants (n=231)

Characteristics	Number	Percent
Gender n (%)		
Male	154	66.7
Female	77	33.3
Age (years) n (%)		
Less than 50	8	3.5
50-59	43	18.7
≥ 60	180	77.9
Mean± S.D. = 66.85 ±8.65		
Education n (%)		
Primary	159	69.4
Secondary	53	23.1
Bachelor	17	7.4
Marital status n (%)		
Married	175	75.8
Unmarried	56	24.2
Comorbidity n (%)		
No	127	55.2
Yes	103	44.8
Cancer stage at diagnosis n (%)		
I	21	9
II	28	12.1
III	96	41.6
IV	70	30.3
Unknown	16	7
Metastasis n (%)		
No	88	38.1
Yes	143	61.9

Table 2. Standardized Factor Loading of the T-CaSUN

The T-CaSUN items	Factor 1	Factor 2	Factor 3	Factor 4
	Intensive care	Information	Relationship	Medical care
10. Reduce stress in my life	0.92			
19. Cancer recurrence concern	0.88			
20. Emotional support	0.79			
24. Talk to other	0.92			
30. Cope with changes of belief	0.85			
33. Deal with uncertainty	0.98			
34. Explore spiritual beliefs	0.77			
35. Make my life count	0.89			
1. Up to date information		0.99		
2. Information for family/partner		0.94		
3. Understandable information		0.95		
21. How to support partner			0.93	
22. Relationship with partner			0.54	
27. Address problem with sex life			0.96	
4. Better medical care				0.65
5. Health care service available				0.46
6. Manage health with team				0.78
7. Doctor talk to each other				0.65
8. Complete address				0.65
Eigenvalues	5.49	3.26	2.13	1.24
% Of variance	31.01	18.41	12.02	7
Cumulative%	31.01	49.42	61.44	68.44

The T-CaSUN, The Thai Cancer Survivor's Unmet Needs

items spread across four components. The Parallel analysis of the factor components of the T-CaSUN.CFA measuring model is shown in Figure 1. The model showed satisfactory fit to the data based on the 5 predetermined fit criteria ($\chi^2/df=1.341$, CFI =0.98, and RMSEA=0.039 (95%CI: 0.023–0.051). All items in the model were loaded substantially on their respective factors (all p-value <0.05), with the exception of each factor-constraint item

which no significance test could be undertaken (Table 2).

The KMO value was 0.87, and the Bartlett sphericity test result was significant ($\chi^2 = 4789.931$, $df=190$, p-value <0.001), indicating that the data were sufficient for the factor analysis.

Convergent validity

Demographic characteristics of the participants were

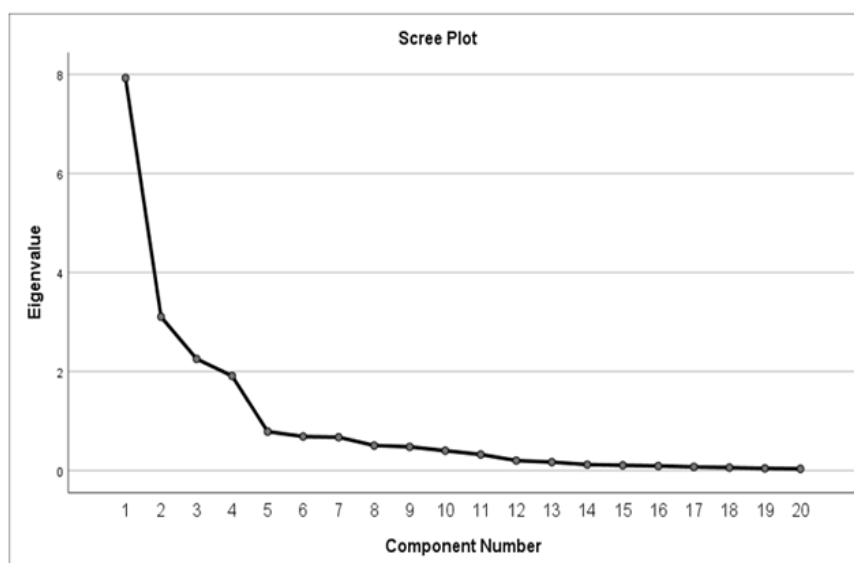


Figure 1. Parallel Analysis of the Factor Components of the T-CaSUN.

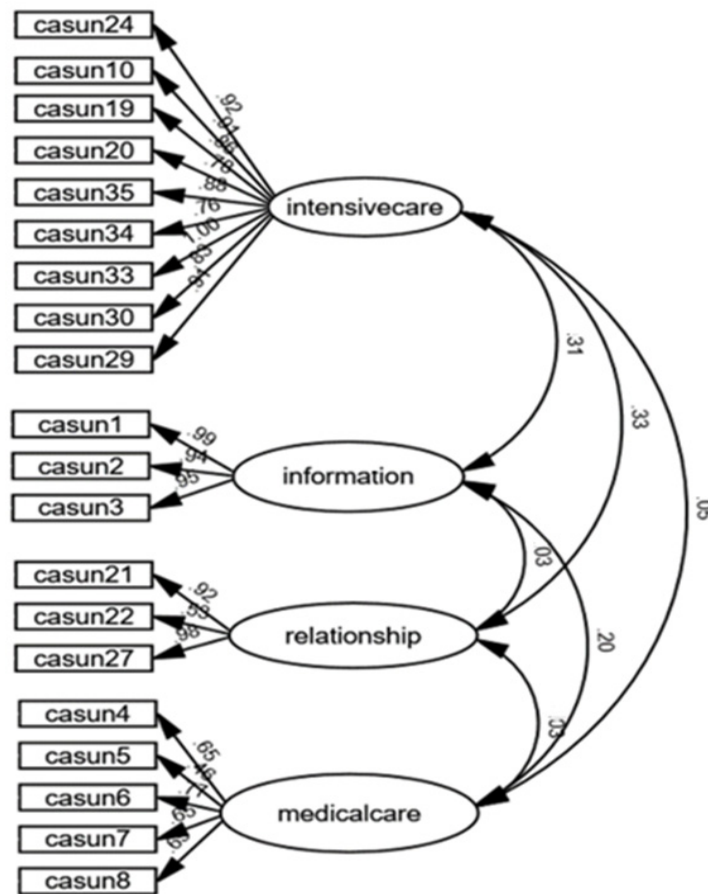


Figure 2. Structure Model of the T-CaSUN with Standardized Path Coefficient

used to explore the correlation between a total of T-CaSUN scores and psychological and physical symptoms variables. Various T-CaSUN subscales were found to be linked with anxiety and depression from HADS subscales, stage of cancer, and age (Table 3).

Internal consistency

The internal consistency of the T-CaSUN was satisfactory with The Cronbach's alpha value of 0.79 for the overall scale result (Table 3).

Inter factor correlations

The inter factor correlations of the T-CaSUN subscales show that intensive care was weakly significantly connected with information care relationship and medical care subscale. Likewise, information care subscale has a weakly positive relationship and medical care, and

relationship has a weakly positive relation with medical care (Figure 2).

Discussion

The results of this study demonstrate that the T-CaSUN has good psychometric properties and it is valid for using in CCA survivors with high acceptability and comprehensibility. Our results confirm that the T-CaSUN instrument consisted of 20 items that are distributed across four factors as follows: Intensive care (9 items), information (3 items), relationship (3 items), and medical care (5 items) on the CaSUN scale for this population.

Internal consistency of the T-CaSUN was good ($r = 0.79$, factor loading score range = 0.46-0.96). These results were comparable to the original CaSUN by Hodgkinson et al (Hodgkinson et al., 2007), and the Dutch (Keeman et al., 2018), Spanish (Tyson et al., 2018), Chinese (Li et al., 2020) and Japanese (Komatsu et al., 2020) CaSUN version. The high internal consistency

Table 3. The Convergent and Discriminant Validity for the Subscale of T-CaSUN

Variable	Total score of T-CaSUN	p-value
Convergent validity		
HADS	0.271	0.002
MSAS-SF-T	0.138	0.023
T-SCNS-P&C	0.148	0.001
Discriminant validity		
Age	-0.334	0.001
Stage at diagnosis	0.148	0.025

Table 4. The Cronbach's Alpha Results of each Subscale of T-CaSUN.

Scale	Cronbach's alpha	95% CI
Intensive care	0.76	0.74-0.78
Information	0.78	0.65-0.81
Relationship	0.85	0.74-0.91
Medical care	0.75	0.65-0.81

of CaSUN in different cultural contexts, including this study, shows the evidence of its strong reliability and indicates that this tool is well designed and eligible to answer the question in the short time, as shown by the participants' comments. This documentation confirms that the T-CaSUN were meaningful and valued for the Thai CCA survivors.

There has been no research in Thailand's CCA population that have investigated the psychometric qualities of a resilience scale. Researchers looking into the CCA population are likely to find our findings useful. Our research found that CCA survivors with symptoms of anxiety, distress, and depression, high caregiver supportive care needs, advanced stage at diagnosis, and old age are more likely to report higher demands of unmet needs. This study also indicated a link between unmet needs with anxiety and depression, which was similar to prior research in different language versions of the CaSUN (Ferrari et al., 2019). We hypothesized that the patients would be anxious and concerned about their disease progression and many adverse treatment effects (pain, etc.) prior to starting treatment because they not only had no knowledge about health intake adjustments, self-care during and after course of treatment, but also could not manage their physical symptoms. As a result, we feel that identifying of unmet needs is a crucial metric for psychological well-being. Patients are given insufficient information to suit their demands, which can lead to psychological and emotional pressures including worry and sadness (Faller et al., 2016). Similarly, anxious patients often experienced with higher levels of physical, psychological, healthcare, and information unmet needs, which was founded across several prior studies (Liao et al., 2011; Uchida et al., 2011; Hasegawa et al., 2016). Patients need health-related information and medical information to support their medical decision-making (Berland et al., 2001). In the outpatient setting, the interaction and communication skills between the patients and healthcare personnel were critical for the patients' ability to cope with cancer (Prip et al., 2018); hence, the findings of these investigations confirm our conclusion. Furthermore, our research found that a total score of unmet needs in CCA survivors was significantly correlated with physical symptoms, possibly because CCA survivors are expected to experience symptoms related to disease and treatment, such as pathological, surgery, chemotherapy, and/or radiotherapy. Our studies demonstrated that the CCA survivors suffering from serious physical illness may experience with one or many symptoms related cancer such as itching, indigestion, anorexia, abdominal pain, fatigue, fever, and sleep disturbance of which are commonly physical illness of CCA, and the association between unmet needs and physical effects have been shown (Molassiotis et al., 2017). In addition, patients with high levels of anxiety and depression were correlated with the highest levels of severe symptom occurrences as well (Chen et al., 2016), so these studies have shown strong support for the construct validity of the T-CaSUN. Likewise, lower ages after receiving main treatment were also found to have negative association with a total score of unmet needs ($r = -0.334$, p -value < 0.001). This outcome

has been regularly observed in several investigations (Keeman et al., 2017), younger CCA patients have a larger need than older patients since they still work to support themselves and their family and are aware that CCA is a serious and incurable illness with a bad prognosis (median overall survival less than one year). Furthermore, our findings revealed that unmet need is positively related to stage at diagnosis, patients with advanced CCA frequently experiencing varying unmet needs over time due to rapid progression of disease (Waller et al., 2012), and expected to advanced stages of disease. Patients with advanced stage of cancer often have symptoms that differ from those with early-stage. Patients with stage 4 of cancer had higher unmet requirements than those with stage 3 of cancer, according to two studies (Hwang et al., 2004; Au et al., 2013). Similarly, our research found that T-SCNS-P&C was linked to CCA's unmet need, implying that high-quality, patient-and-family-centered care was required to manage the issues faced by both advanced CCA patients and their caregivers, such as symptom and side effect care, as well as psychosocial, emotional, and spiritual support (Wang et al., 2018). Caregiving responsibilities include monitoring patient's symptoms, dealing with unpleasant side effects, and providing instrumental and emotional supports to the CCA patients.

This research has some limitations as a number of methodological flaws. First, we considered CCA survivors from a single university hospital in Thailand, so they were not presentative of this all of CCA population. Second, while the CFA backed the scale's initial model, we should be aware that several of their items had low factor loadings and substantial residual errors.

In conclusion, the T-CaSUN was found to be a relevant and reliable measure for assessing unmet needs in the CCA survivors. T-CaSUN has the ability to find the most effective treatments for cancer survivors on an individual basis. The current study highlighted unmet health, personal care, and social care needs among CCA survivors. One of the primary elements for ensuring proper care for CCA survivors is to do a care needs assessment. Nurses may give focused interventions and tailored care based on the assessment of unmet needs to improve the patients and their families' QOL. Healthcare professionals can design evidence-based and personalized therapies for patients with advanced malignancies if they have a thorough grasp of their unmet requirements.

Author Contribution Statement

MS., PR., BP. envisioned the research idea. US. and MT. analyzed, interpreted the data, and helped to draft the manuscript. That was also discussed with US and ST. who supervised the research project. All authors revised the manuscript critically and approved the final version to be published.

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Ethical Approval

This research was approved by the research ethics committee of Khon Kaen University, Thailand (HE631628). The informed written consent was obtained from each of the study participants of this study. Besides, every participant was assured about the confidentiality of his personal information.

Availability of the data

Data can be provided on a duly justified request to the corresponding author.

Conflicts of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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