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Research Article

Design and Psychometrics of a Supportive and Palliative Care Needs Assessment Tool for Cancer Patients

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ABSTRACT

Background: Supportive and palliative care is recognized as an important and vital component of cancer patient care. Utilizing an appropriate instrument can identify these needs. This study aimed to "design and psychometrically evaluate an instrument for assessing the supportive and palliative care needs of cancer patients."

Methods: This study is a methodological research with both qualitative and quantitative components. Participants included 210 cancer patients. Questionnaire items were extracted through qualitative study methods and literature review, and subsequently, an initial questionnaire was designed. The validity of this questionnaire was evaluated through content, construct, and face validity assessments. Internal consistency and stability of the questionnaire were also examined to determine its reliability.

Results: 59 items were extracted from the qualitative section and literature review. Subsequently, the Item Impact Score (values above 1.5) was calculated. The CVI (above 0.79) and CVR (above 0.56) were assessed, resulting in the selection of 35 items. Exploratory factor analysis yielded four factors: symptom and pain control (6 items), psychological and social needs (17 items), spiritual needs (4 items), and education and awareness (8 items). Finally, a 35-item questionnaire was designed, demonstrating acceptable reliability (α=0.90).

Conclusion: The questionnaire designed in this study has acceptable and confirmed psychometric properties (validity and reliability). Therefore, the use of this instrument is recommended for Iranian patients with cancer.

Introduction

Cancer is a prevalent disease worldwide, capable of affecting any organ in the body. It can subsequently spread to and involve other organs. Cancer is also commonly known as neoplasm or malignant tumor [1]. This disease poses significant challenges to global healthcare systems. In 2023 alone, nearly two million new cancer cases (approximately 5,370 per day) and over 600,000 deaths due to the disease were reported in the United States [2]. According to the Global Burden of Disease data, in Iran, the mortality rate and DALYs (Disability-Adjusted Life Years) due to cancer were 96 and 2321 per 100,000 in 2019, respectively [3]. Iragorri et al. (2021) write in this regard: cancer imposes significant costs on healthcare systems, cancer patients, and their families. The researchers reported that the monthly cost of this disease (cancer) is high in different countries, for example in the United States ($180 to $2,600), Canada ($15 to $400), Europe ($4 to $609), and Australia ($58 to $438). Also, each patient in low-income countries spends about 42% of their annual capital on disease-related costs [4]. The World Health Organization states that the global cancer burden is increasing, creating significant economic, emotional, psychological, and physical challenges for individuals and society. Many low-income countries are ill-equipped to manage this disease effectively, leaving

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numerous patients facing severe difficulties and lacking access to necessary treatment and care [1]. Cancer and its treatments result in numerous consequences for patients, spanning physical, psychological, and social domains. For example, physical consequences include cardiac dysfunction, peripheral neuropathy, metabolic syndrome, lymphedema, osteoporosis, and pain. Immunotherapies can have specific effects on the gastrointestinal tract, liver, endocrine system, and skin. Many problems arise in these patients after cancer, such as fear of recurrence, cognitive disorders, sleep pattern problems, financial and career problems, sexual dysfunction, and fatigue [5]. Treatment options for cancer patients include radiotherapy, chemotherapy, surgery, or a combination thereof. A multidisciplinary team of cancer specialists will recommend a treatment plan tailored to the type and stage of cancer and other related factors. Ultimately, the treatment is chosen based on patient preferences and the capabilities of the healthcare system [1]. Mortality rate is a good measure for evaluating treatment and progress against cancer because it is less susceptible to biases. One of the most important reasons for the decline in cancer mortality in recent years is early detection, treatment, and standard care for cancer patients [2]. Traditional cancer care models often fall short in adequately addressing the psychological, social, physical, and supportive needs of patients [5]. Supportive and palliative care, widely recognized in cancer management, offers significant assistance to these patients. In the context of supportive and palliative care for cancer patients, the World Health Organization emphasizes that these types of care are an essential component of cancer patient management, as they improve quality of life. This care should include a detailed plan for monitoring new cancer diagnoses, disease recurrence, assessment and management of cancer complications and treatments, as well as services to meet the needs of cancer patients [1]. Palliative care is defined as a type of care provided by a specialized team based on the needs of patients at any stage of the disease and for all patients. The effects of palliative care for patients with cancer include reducing physical and psychological problems, which improves the quality of life of patients. However, significant advances in the treatment of these patients have led to changes in the palliative needs of patients. Therefore, further research in this area is necessary [6].

Using a supportive and palliative care screening tool can identify patients' needs and help address them [5]. A systematic review by Teike Lüthi et al. (2022) evaluated palliative care needs instruments for cancer patients and found that there was low-quality and incomplete evidence for determining patients' palliative care needs. This issue could be addressed by conducting further research on existing instruments or by developing a locally adapted instrument to identify palliative care needs in cancer patients [7]. Questionnaires designed in a specific country reflect the language and culture of that society. Consequently, even with accurate translation, they may not effectively measure the intended variable when used in another society due to content mismatch. Therefore, it is necessary to design questionnaires tailored to the culture of that country.

Considering the above and the need for valid and reliable instruments that are native and appropriate for the cultural and social context of our society in cancer patients, the purpose of this study is to "design and psychometrically evaluate a support, palliative, and care needs assessment tool for cancer patients."

Methods

This is a methodological study conducted on cancer patients. The research population is patients referred to the medical centers of the University of Tehran. The sampling method was purposive. The inclusion criteria for the study were age over 18 years, informed consent, proficiency in Persian, ability to express experiences, and definitive diagnosis of cancer by a specialist. Patients with cognitive impairment or unwillingness to continue participation were excluded from the study.

This research was conducted in a mixed (qualitative and quantitative) manner. As the first step, semi-structured interviews were conducted with cancer patients diagnosed by specialists, regardless of their educational level, occupation, or social status, and including both genders. These interviews were analyzed using a content analysis approach. In this process, data collection focused on defining the concept of supportive palliative care and determining its dimensions and items, aligning with the research objective. Subsequently, relevant studies and articles on instrument development, as well as separate supportive and palliative needs assessment tools, were reviewed and examined. For this purpose, databases such as Ovid, Science Direct, PubMed, Google Scholar, and Iranian databases like Mag Iran and SID were searched without any time restriction using the following keywords: cancer, palliative care, supportive care, supportive needs, palliative needs, supportive and palliative needs tool/scale/questionnaire, palliative care tools, and combinations of these keywords. Subsequently, the following steps were taken.

In the first phase, the concept of supportive and palliative care was defined based on the perspectives of these patients and the literature review. Next step, the dimensions of the instrument and the items related to each dimension were determined based on the perspectives of the aforementioned participants and a review of the literature. After defining the concept and determining the dimensions and items of the instrument, the collected data were reviewed by the researchers in meetings. Some items were merged or deleted, and some were modified. As a result, a preliminary instrument was designed to assess supportive and palliative care needs. The response scale for the questions is a five-point Likert scale. In the final (third) stage, after designing the preliminary instrument, psychometric evaluation was conducted. The validity of this questionnaire was evaluated through content, construct, and face validity assessments. Internal consistency and stability of the questionnaire were also examined to determine its reliability.

Assessing Face Validity

Face validity was determined using the opinions of 10 cancer patients (qualitative method) and 10 experts (quantitative method). In the qualitative method, face-to-face interviews were conducted with patients to examine the level of difficulty and relevance of the questions. In the quantitative method, the question impact method was used. A score of 1.5 or higher was considered an acceptable impact score [8-9].

Content Validity Assessment

In this section, qualitative and quantitative methods were used. In the qualitative phase, the content coverage, grammar, appropriate use of language, and placement of items were evaluated based on feedback from 11 cancer-related experts. In the quantitative phase, CVI and CVR were used. The opinions of the same 11 experts were collected. For the Content Validity Index (CVI), three criteria—relevance, simplicity/clarity, and clarity/transparency—were assessed for each question using a 4-point Likert scale. An item was considered acceptable if the score was above 0.79, requiring revision if between 0.70 and 0.79, and unacceptable (and thus removed) if below 0.70. The S-CVI (Scale-level CVI) was calculated and a score of 0.9 or higher was considered acceptable [9]. The content validity ratio (CVR) was determined based on expert opinion and whether the questionnaire questions were unnecessary, necessary, or useful but not essential. A CVR coefficient greater than 0.56 was considered acceptable [9].

Construct Validity Assessment

Factor analysis was used in this section. The sample size was considered to be 5-10 participants per item [9]. Therefore, in our study, given the number of items, the sample size was 240 participants, and convenience sampling was used. After explaining the research objectives and ensuring confidentiality of information, written informed consent was obtained, and questionnaires were completed by the participants. The acceptable value for KMO (Kaiser-Meyer-Olkin) is 0.60 [9]. Bartlett's test of sphericity was also used. Exploratory factor analysis was used. Principal component analysis with Varimax rotation was also used for this analysis. Eigenvalues and score plots were also considered to determine the number of factors. The factor loading of each question in the rotated factor matrix was set at a minimum of 0.40 [9].

Reliability Assessment

Internal consistency and stability were used in this section. Stability was also assessed using test-retest. A Cronbach's alpha value above 0.6 was considered an acceptable criterion [9]. Internal consistency was evaluated on 240 cancer patients. To determine stability, the test-retest method and Intraclass Correlation Coefficient (ICC) were used. A minimum ICC of 0.4 was considered acceptable [9]. The test-retest of the questionnaire was performed on 25 cancer patients in two stages, approximately two weeks apart, and the Intraclass Correlation Coefficient was calculated for all questions and the entire questionnaire.

Data Analysis

The collected data were analyzed using SPSS software version 25. A P value of <0.05 was considered as our criterion.

Results

The initial questionnaire was designed based on interviews with 18 cancer patients (results of the qualitative phase) and a review of the existing literature in this field, including 59 questions. These questions pertained to the experiences of cancer patients regarding supportive and palliative care needs. Six questions related to demographic characteristics were also added to the questionnaire. These questions were about sex, age, occupation, marital status, education of the participants, and time since cancer diagnosis. Findings from qualitative face validity assessment indicated that 5 items required revision in terms of difficulty level, relevance, and ambiguity, which were subsequently modified. A 5-point Likert scale was adopted, with options ranging from "very high " to "very low." In the quantitative face validity assessment, 8 items, including "I need permanent injection (pain pump) or continuous analgesic consumption"; "I need periodic consultation with a pain specialist"; "I need diarrhea management"; "I need hope along with realistic information from the treatment team"; "I need to eliminate my worry and distress due to family discomfort"; "I prefer to be with my family instead of being hospitalized"; "After contracting the illness, I have developed a greater need to connect with God"; "I am interested in learning about hospital rules and regulations," were removed due to scoring less than 1.5 on the impact score. Consequently, the number of items decreased from 59 to 51, and these 51 items were retained for content validity assessment. Based on qualitative content validity, considering content coverage, grammar adherence, appropriate phrases, and the proper placement of the initial questionnaire questions, 11 questions were modified. Due to the content validity ratio, 10 questions with coefficients lower than the set threshold were removed, reducing the total number of items to 41. Subsequently, after calculating content validity for the questionnaire items, 6 items were removed because they scored below the acceptable CVI threshold. Based on the average CVI scores, the questionnaire's average S-CVI/Ave was calculated to be 0.90, which is acceptable. At this stage, the final instrument consisted of 35 items and proceeded to the next stage (construct validity).

Construct validity was assessed in a sample of 210 patients who met the study inclusion criteria (e.g., age over 18 years, willingness to participate, a cancer diagnosis by a specialist physician for over a year). Demographic characteristics are presented in (Table 1).

Based on Bartlett's sphericity test, the correlation between variables ($p \leq 0.001$) and the Kaiser-Meyer-Olkin value (KMO=0.842) were acceptable. Exploratory factor analysis resulted in four factors: symptom and pain control (comprising 6 items), psychosocial needs (17 items), spiritual needs (4 items), and education and awareness (8 items). Finally, the Supportive and Palliative Care Needs Assessment Questionnaire for Patients with Cancer was developed with 35 questions, and the steps and process of item reduction are presented in (Table 2). The reliability results indicated that the instrument's Cronbach's alpha coefficient (0.90) was acceptable. Considering the consistency coefficient results (0.898) and the significance level ($P \leq 0.001$), the questionnaire's stability over time was confirmed. The intra-class correlation coefficient for all items and dimensions of the questionnaire is presented in detail in (Table 3).

Table 1- Demographic characteristics of cancer patients (n = 210)

Variables		N	%
Gender	Female	115	54.7
	male	95	45.3
Age	18-29	14	6.6
	30-39	31	14.9
	40-49	93	44.3
	50-59	55	26.1
	60 and older	17	8.1
Marital status	Single	53	25.3
	Married	157	74.7
Education level	Undergraduate	79	37.6
	Diploma	86	41
	University	45	21.4
Job	Unemployed	23	10.9
	Employee	39	18.6
	Freelance	53	25.3
	Housewife	95	45.2
Duration of disease (years)	Less than one year	85	40.5
	1 - 5	94	44.7
	5 - 10	24	11.4
	Above 10 years	7	3.4

Table 2- Stages of questionnaire item reduction in different phases of validation

Item Reduction Steps	Initial Items	Modified Items	Deleted Items	Remaining Items
Initial item pool	191	-	-	191
Review by researchers	191	-	132	59
Qualitative face validity	59	5	-	59
Quantitative face validity	59	-	8	51
Qualitative content validity	51	11	-	51
Content Validity Ratio (CVR)	51	-	10	41
Content Validity Index (CVI)	41	-	6	35
Construct validity	35	-	-	35

Table 3- ICC values for factors of the questionnaire on supportive and palliative care needs of cancer patients

Dimensions	ICC	CI=95%		Significant level
		Lower limit	Upper limit	
Symptom and Pain Management	0.921	0.918	0.937	$P \leq 0.001$
Psychological and Social	0.838	0.789	0.869	$P \leq 0.001$
Spiritual	0.825	0.821	0.875	$P \leq 0.001$
Education and Awareness	0.902	0.879	0.918	$P \leq 0.001$
Total	0.903	0.878	0.921	$P \leq 0.001$

Discussion

The questionnaire of the present study consists of 35 questions and four dimensions: symptom and pain management (6 items), psychological and social needs (17 items), spiritual needs (4 items), and education and information (8 items). Each of these dimensions is essential to the questionnaire. Research has shown that palliative care offers significant benefits in various physical, psychological, quality of life, and other aspects for cancer patients. Significant advances in the treatment of these patients have led to changes in their supportive and palliative care needs, thus necessitating further research in this area [6]. Using a supportive and palliative care screening tool can identify patients' needs and help address them [5]. Accordingly, the questionnaire designed in our study can effectively identify the needs of patients, particularly Iranian patients, and pave the way for improving their quality of life. Compared to other similar indigenous questionnaires [10-12], our study questionnaire examines the needs of cancer patients in more dimensions (physical, psychological, social, spiritual, and informational). For example, the indigenous questionnaire by Koohkan Aliabadi et al. (2019) addresses the health information needs of families of children with cancer, the questionnaire by Riahi et al. (2016) addresses the health information needs of immigrants with cancer, and the questionnaire by Shokouhi et al. addresses the spiritual needs of cancer patients [10-12]. It is worth mentioning that the needs expressed in these tools are also present in our study questionnaire, which is considered a strength.

In our study, the first dimension of the questionnaire is "Symptom and Pain Control." The items in this dimension reflect the physical needs of patients affected by cancer and its treatments. Badiyepeyma et al. (2024) state that cancer is a physically threatening disease that affects various aspects of an individual's life. Patients undergoing treatment often face numerous challenges, with pain being one of the most common. These researchers concluded that reducing pain through non-pharmacological therapies alongside medication can significantly improve physical health [13]. Similarly, our study emphasizes the necessity of symptom and pain control as a primary need for these patients.

The second dimension of our study's questionnaire concerns "psychological and social needs." The items in this dimension explore the "psychological needs" that arise in patients following a cancer diagnosis, as well as the "social needs" that can help patients manage the disease. Cancer causes various physical and psychological harms to those affected. Due to the lack of a cure, disease recurrence, and metastasis, cancer patients experience significant psychological problems such as anxiety, stress, depression, etc., highlighting the necessity of employing different strategies to identify these problems and plan to address them [14]. Our questionnaire items also examined various psychological needs. For example, the item "I must maintain my spirit and not despair" or the item "I must control my negative emotions such as irritability, stress, depression, and anxiety" is relevant in this regard. Furthermore, the items "The treatment team (nurse and doctor) needs to pay more attention to my psychological needs" and "I need to improve my mental health (travel and recreation, nature, entertainment)" explore the importance of addressing psychological needs in these patients.

High social support in cancer patients significantly reduces disease symptoms [15]. Social support is an interaction that begins with communication, fosters empathetic connection with the patient, and ultimately forms a safe network for patients [16]. Nahtani and Peyman (2024), in a systematic review on social support in cancer patients, reported that with more support for these patients, their quality of life increases significantly. Social support consistently has a positive impact on reducing the negative effects of cancer-related thoughts, resilience, coping style, and more. Researchers have reported that the types and sources of social support vary across cultures. For example, some cultures emphasize family support, while others prioritize community or peer support [17]. In our study's questionnaire, the social dimension section examines patients' various needs. For instance, the statement "I need support from the government and society (financial, insurance, etc.)" emphasizes community support, and the statement "I need emotional support from family and friends" emphasizes family and friend support. Furthermore, our study questionnaire includes items related to other forms of social support, such as financial and employment assistance and access to self-help groups and associations, which is a strength.

The third dimension of our study's questionnaire is "Spiritual Needs." Providing quality spiritual care to cancer patients requires a deep understanding of their spiritual needs. Recognizing patients' spiritual experiences helps the treatment team deliver care tailored to these needs [13]. Personal experience, race, and culture can influence the expression of an individual's spirituality; Each person has their own understanding of spirituality [18]. Consequently, the inclusion of the spiritual needs dimension in our study's questionnaire is considered a strength. The results of the Tavakkol et al. (2024) study indicated that cancer causes changes in the life path, attitudes, and spiritual and religious beliefs of those affected. This disease can also significantly contribute to the spiritual growth and transcendence of patients. These researchers suggested that spiritual needs should be considered an important part of comprehensive care for cancer patients. They also recommended further research into addressing these needs in cancer patients

[19]. The items in our study's spiritual dimension also reflect the importance of these needs in cancer patients. For example, the items "I need spiritual support to gain more peace" and "Worshiping God (praying and reading prayers) and going to religious places help me feel calm" confirm this issue.

The fourth dimension of our study questionnaire is "Education and Awareness." This dimension emphasizes increasing awareness and providing education tailored to the needs of cancer patients. For example, statements such as "I need to gain more information about self-care" or "I need education regarding the disease, complications, treatment, and prognosis" fall into this area. Furthermore, this section of our questionnaire emphasizes the need for education and increased awareness not only for patients but also for their families and those around them. For instance, the statement "My family and those around me need to be educated by the treatment team (psychiatrist, treating physician, nurses)" explores this issue. Nematpour et al. (2024) reported in a study that cancer improvement program training is effective in reducing symptoms, pain, and perceived stress in cancer patients. These researchers suggested that educational programs and increased awareness should be utilized for cancer patients in counseling and psychotherapy centers active in welfare and treatment centers [20]. In this context, Imani et al. (2021) concluded in a study on cancer patients that if the patient's need and desire for access to information are considered, it can shorten the treatment, recovery, and prevention of secondary complications of the disease and the convalescence period. If the caregiver understands the patient's language and educates the patient in that spoken language, knowledge transfer will occur with greater speed and quality [21].

Conclusion

The Palliative and Supportive Care Needs Assessment Questionnaire for Patients with cancer (PCN-35) possesses acceptable and validated psychometric properties (validity and reliability). Considering the four extracted dimensions in this questionnaire, including symptom and pain control, psychosocial needs, spiritual needs, and education and awareness, it can be stated that the present questionnaire addresses the various needs of Patients with cancer. Therefore, the use of this questionnaire is recommended for assessing the palliative and supportive care needs of Patients with cancer.

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