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Relationship Between Spiritual Care Needs and Sleep Quality in Older Patients with Cancer

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ABSTRACT
Objective: To investigate the spiritual care needs and sleep quality of older patients with cancer and determine the relationship between these variables. **Materials and Methods:** Research was conducted with 174 older patients with cancer. Data were collected using Introductory Information Form, Spiritual Care Needs Inventory, Pittsburgh Sleep Quality Index. Data were analyzed using Independent Two Sample T, Mann Whitney U, One-Way Analysis of Variance and Pearson Correlation Tests. **Results:** The spiritual care needs of those who were married, never used caffeine, used traditional treatment, and who could not fulfill their religious activities during cancer process were higher. Participants with additional chronic diseases had poor sleep quality. 71.8% of participants had poor sleep quality, 58.3% of those had high spiritual care needs. According to mean scores of the scales, participants had moderate spiritual care needs, poor sleep quality. No significant relationship (r= -0.026; p=0.733) was found between spiritual care needs and sleep quality. **Conclusion:** Although there was no relationship between spiritual care needs and sleep quality of older patients with cancer, they had spiritual care needs and their sleep quality was poor. The spiritual care needs of this population should be met and interventions to improve sleep quality should be planned.
Keywords: Nursing, Cancer Care, Spiritual, Sleep, Older Health.

Yaşlı Kanser Hastalarında Spiritüel Bakım Gereksinimi ile Uyku Kalitesi Arasındaki İlişki

ÖZ
Amaç: Yaşlı kanser hastalarında spiritüel bakım gereksinimlerinin ve uyku kalitelerinin belirlenmesi ve değişkenler arasındaki ilişkinin saptanması amaçlanmaktadır. **Gereç ve Yöntem:** Araştırma 174 yaşlı kanser hastası ile yürütüldü. Veriler, Tanıtıcı Bilgi Formu, Spiritüel Bakım Gereksinimleri Ölçeği ve Pittsburgh Uyku Kalitesi Ölçeği ile toplandı. Veriler Bağımsız İki Örnek T, Man Whitney U, Tek Yönlü Varyans Analizi ve Pearson Korelasyon Testleri ile analiz edildi. **Bulgular:** Evlilerin, hiç kafein kullanmayanların, geleneksel tedavi kullananların, kanser sürecinde dini aktivitelerini hiç yerine getiremeyenlerin spiritüel bakım gereksinimlerinin daha yüksek olduğu belirlendi. Ek kronik hastalığı olanların uyku kalitesinin daha kötü olduğu saptandı. Katılımcıların %71.8'inin uyku kalitesinin zayıf ve %58.3'nün bakım gereksinimlerinin yüksek olduğu bulundu. Katılımcıların genel ölçek puan ortalamalarına göre spiritüel bakım gereksinimlerinin orta düzeyde ve uyku kalitelerinin kötü olduğu belirlendi. Yaşlı kanser hastalarında spiritüel bakım gereksinimleri ile uyku kalitesi arasında anlamlı bir ilişki (r: -0.026; p: 0.733) olmadığı ortaya çıktı. **Sonuç:** Yaşlı kanser hastalarının spiritüel bakım gereksinimleri ve uyku kaliteleri arasında ilişki bulunmamasına rağmen, spiritüel bakım gereksinimleri olduğu ve uyku kalitelerinin kötü olduğu belirlenmiştir. Bu hastaların spiritüel bakım gereksinimleri karşılanmalı, uyku kalitesini arttırmaya yönelik girişimler planlanmalıdır.
Anahtar Kelimeler: Hemşire, Kanser Bakım, Spiritüel, Uyku, Yaşlı Sağlığı.

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INTRODUCTION

According to the World Health Organization's GLOBACAN (Global Cancer Observatory) 2020 data, 12,355,723 individuals aged 60 years and over worldwide had cancer; 13.6% of these older patients had lung cancer, 11.4% had colorectal cancer, 9.8% had prostate cancer, 8.3% had breast cancer, and 6.4% had stomach cancer (World Health Organization, 2024). Both age-related physiological changes and cancer have a negative impact on quality of life. In addition, due to cancer and its treatment, physical and cognitive aging accelerates biologic aging with DNA damage, energy decrease, frailty, sleep disturbances, and stress increase (Carroll et al., 2022). Older individuals have to cope with the cancer treatment process and its effects. In this sense, National Comprehensive Cancer Network (NCCN) "Older Adult Oncology" version 1.2023 guide recommends comprehensive care needs to be provided for older patients (National Comprehensive Cancer Network, 2024).

It is important to evaluate spirituality, which is overlooked in older patients with cancer but is a part of the holistic approach. On the other hand, spiritual care plays a role in strengthening patients' communication, accelerating recovery, reaching peace, giving meaning to lives, and developing stress coping strategies (İsmailoğlu et al., 2019). In a study, it was stated that the pain and anxiety of patients with cancer who received spiritual care decreased (Ratshikana-Moloko et al., 2020). In another study, it was determined that almost all patients with cancer needed spiritual care, and it was reported that those who received less spiritual care experienced less peace and more depression (Pearce et al., 2012).

Another situation that should be evaluated in older patients with cancer is sleep, which is a natural process in which the body rests for a certain period and brain activity changes and consciousness decreases (Carroll et al., 2022). It has been reported that many factors such as pain, fatigue, and anxiety cause sleep disorders in older patients with cancer (Loh et al., 2017), and insomnia is observed at a rate of 25% to 69%, depending on the type of cancer (National Comprehensive Cancer Network, 2024). A study reported that 89.7% of patients with cancer aged over 65 years had poor sleep quality. It has also been stated that sleep quality worsens 1.04 times with aging (Endeshaw et al., 2022). Insufficient sleep causes many negative effects such as delay in the elimination of metabolic wastes, stress, fragility, development of inflammation, pain, negative emotions, depression, fatigue, and memory problems (Carroll et al., 2022).

Although no significant results were found in a study evaluating the relationship between sleep quality and mental well-being in women with breast cancer, it was stated that there was a significant relationship between sleep transition and sleeping pill use and religious activities (Khoramirad vd., 2015).

A review has shown that a wide variety of techniques such as mantra, yoga, mindfulness, prayer/meditation, daily spiritual experiences, psycho-religious education, and intervention are used to treat insomnia or insomnia-related mental disorders in adults, and as a result, spirituality has a direct and indirect positive effect on insomnia (de Diego-Cordero et al., 2022). Therefore, because it is thought that there is a relationship between sleep and spiritual care, it is important to evaluate this relationship in older patients with cancer.

Older patients with cancer need to be evaluated for both insomnia and spiritual care needs to strengthen their ability to cope with their symptoms. Research has shown that spiritual care increases sleep quality in patients with cancer (Wang & Lin, 2016). However, no studies have been found in the literature that determine the relationship between the need for spiritual care and sleep quality in older patients with cancer. The NCCN guideline also recommends providing spiritual care to older patients with cancer and evaluating patients for sleep disorders (National Comprehensive Cancer Network, 2024). For this reason, it was aimed to determine the spiritual care needs and sleep quality of older patients with cancer and establish the relationship between them.

Research questions

• What is the level of spiritual care needs in older patients with cancer?
• How is the sleep quality in older patients with cancer?
• Is there a correlation between spiritual care needs and sleep quality in older patients with cancer?

MATERIALS AND METHODS

Research type

This research was descriptive and correlation-seeking. The STROBE guideline was used in reporting the research.

Research sample

Approximately 450 older patients with cancer are admitted to the Training and Research Hospital oncology outpatient clinic and inpatient clinic per month. The sample was determined using the sampling formula with a known population. The acceptable error was 5%, the population size was 450, and the confidence interval was 90%. According to the data, it was calculated that a minimum of 170 patients would be required for the research. The research was completed with 174 patients.

Inclusion criteria

- 65 years of age or older
- Being diagnosed with cancer and knowing that you have been diagnosed with cancer
- To agree to participate in the research
- No communication problems (hearing, vision, speech, etc.)

Data collection

Data were collected in face-to-face interviews with patients between June and July 2023. Data were collected from older patients coming to the oncology outpatient clinic and inpatient clinic with 10–15-minute interviews at 08.00 am until 17.00 pm on weekdays. Preliminary research was performed on 10 patients to evaluate the suitability of the questionnaires, and these data were not included in the data analysis.

Data collection tools

The data were collected using an Introductory Information Form, the Spiritual Care Needs Inventory, and the Pittsburgh Sleep Quality Index.

Introductory information form

This form, which was developed by the researchers through a literature review, consisted of 15 questions including sociodemographic and medical characteristics (Wang & Lin, 2016; Loh et al., 2017; Ratshikana-Moloko et al., 2020). The form included age, sex, education level, marital status, employment status, income status, smoking status, alcohol consumption status, caffeine (coffee) consumption status, type of cancer, cancer treatment, chronic diseases, information about non-medical treatment practices, the status of performing religious activities before the disease process, and the status of performing religious activities during the disease process.

Spiritual Care Needs Inventory (SCNI)

The SCNI was developed by Wu et al. (2016) and the Cronbach's α = 0.96. The Turkish validity and reliability study was conducted by Günay İsmailoğlu et al. (2022), and the Cronbach alpha value was found as 0.94 (İsmailoğlu et al., 2019). The scale consists of 21 items with a 5-point Likert type measuring the potential spiritual care needs of patients. The scale has two sub-scales: "meaning and hope" and "caring and respect." In the meaning and hope subscale, there have been expressions regarding the self, nature, and environmental factors of spiritual well-being, and in the caring and respect component, there are expressions regarding relationships with other people. Higher scores indicate that individuals need more spiritual care (İsmailoğlu et al., 2019). Cronbach's α value of the current research= 0.87.

Pittsburgh Sleep Quality Index (PSQI)

The PSQI was developed by Buysse et al. (1989). Turkish validity and reliability were established by Ağargün et al. (1996), and the Cronbach's α= 0.80. The PSQI consists of a total of 24 questions, 19 questions are answered by the participant and five questions are answered by the patient's sleeping companion, but only the questions answered by the person are evaluated. The scale evaluates sleep quality in the last month; subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency (sleep time/time in bed), sleep disturbance, use of sleeping pills, and daytime dysfunction. Sleep quality is defined as "good" in those whose total score is 5 points or less, and sleep quality is defined as "bad" in those whose score is more than 5 points (Agargun, 1996). Cronbach's α value of the current research= 0.78.

Ethical considerations

Permission for the research was obtained from the Clinical Research Ethics Committee (HRÜ/23.10.27). Permission to use the scale was obtained from the owners of SCNI and PSQI. The patients included were informed about the research aim and that participation was voluntary. Written informed consent was obtained from each participant.

Data analysis

Data were analyzed using the IBM Statistical Package for the Social Sciences (SPSS) V23. Data are presented with number, percentage, mean, standard deviation, median, minimum and maximum. Normality distribution was evaluated using Kolmogrow-Smirnov and Skewness Kurtosis values, and independent two-sample t-test, Mann-Whitney U test, one-way analysis of variance (ANOVA) analyses were used. The correlation between SCNI and PSQI was evaluated using Pearson's correlation analysis. The significance level=$p<0.05$.

RESULTS

The majority (89.7%) of the patients were aged 65-74 years. The majority were women (60.3%), married (91.9%), illiterate (67.8%), had lower income (54.6%), had never smoked (92.5%) or used alcohol (45.4%), used caffeine (55.2%), and were unemployed (97.1%). In addition, the majority of the patients had additional chronic diseases (53.4%), did not use traditional treatment (87.4%), performed religious activities regularly before developing cancer (96.0%), and did not perform religious activities at all during the cancer process (43.7%) (Table 1).

Older patients with cancer who were married had more spiritual care needs than those who were single ($t=8.208$, $p<0.001$), those who never used caffeine had more spiritual care needs than those who used and had quit (Welch=15.279, $p<0.001$), those who used traditional treatment had more spiritual care needs than those who did not use it ($t=2.338$, 0.021), and those who could never perform religious activities during the cancer process had more spiritual care needs than those who did them occasionally or regularly (Welch=15.588, $p<0.001$). In addition, it was found that the sleep quality of patients with additional chronic disease was worse than those without ($t=4.35$, $p<0.001$) (Table 1).

Table 1. Sociodemographics and scale scores of participants (n=174).

Sociodemographic characteristics	n	%	Spiritual care needs inventory			Pittsburgh sleep quality index		
			M±SD	Test statistics	p value	M±SD	Test statistics	p value
Age								
65-74	156	89.7	63.28±13.52	t=0.881	0.379	8.13±4.85	t=-0.027	0.979
75 and over	18	10.3	60.39±9.64			8.17±4.63		
Gender								
Man	69	39.7	63.88±12.27	t=0.73	0.466	8.03±4.55	t= -0.241	0.810
Women	105	60.3	62.39±13.77			8.21±5.00		
Marital status								
Married	160	91.9	63.91±13.31	t=8.208	**p<0.001**	7.96±4.84	t=-1.633	0.104
Single	14	8.1	52.36±3.50			10.14±4.20		
Education status								
Literate	118	67.8	61.77±13.10	F=1.585	0.208	8.06±4.75	F=2.651	0.078
Primary/Secondary school	42	24.1	65.31±14.02			9.14±5.14		
High school/University	14	8.05	66.21±10.15			5.79±3.53		
Income								
Income <Expense	95	54.6	64.51±12.59	t=1.68	0.095	8.31±4.57	t=0.502	0.617
Income≥Expense	79	45.4	61.15±13.71			7.94±5.12		
Alcohol								
Never used	161	92.5	62.57±13.35	t=-1.476	0.142	8.11±4.81	t=-0.251	0.802
Quit	13	7.5	68.15±9.70			8.46±5.01		
Smoking								
Uses	35	20.1	64.40±11.95	F=0.256	0.774	9.40±4.49	F=1.768	0.174
Never used	79	45.4	62.72±13.93			7.57±4.82		
Quit	60	34.5	62.50±12.99			8.15±4.92		
Caffeine								
Uses	96	55.2	64.02±13.33	Welch= 15.279	**p<0.001**	8.29±4.84	F=0.387	0.680
Never used	47	27.0	66.28±13.63			7.62±5.18		
Quit	31	17.8	54.77±7.99			8.45±4.23		
Employment status								
Employment	5	2.9	48(42-77)	U=539.5	0.292	11 (1-13)	U=410.5	0.914
Unemployment	169	97.1	65(21-98)			8 (0-21)		
Additional chronic disease								
Yes	93	53.4	62.44±13.34	t= -0.58	0.563	9.55±4.84	t=4.35	**p<0.001**
No	81	46.6	63.60±13.04			6.52±4.27		
Methods of used outside of medical treatment								
Yes	22	12.6	69.05±10.75	t=2.338	**0.021**	8.86±4.25	t=0.755	0.451
No	152	87.4	62.11±13.29			8.03±4.9		
Attending religious activities before the cancer								
None	3	1.7	68.67±14.01	F=0.397	0.673	4.00±4.00	F=1.711	0.184
Occasional	4	2.3	59.75±15.11			10.75±5.38		
Regular	167	96.0	62.96±13.18			8.15±4.79		
Attending religious activities during the cancer								
None	76	43.7	67.17 ±12.59	Welch= 15.588	**p<0.001**	8.79 ± 4.51	F=2.878	0.059
Occasional	44	25.3	64.50 ±13.34			8.59 ± 5.08		
Regular	54	31.0	55.85 ±10.93			6.85 ± 4.84		

t: Independent two-sample t test, U: Man Whitney u test F: One-way analysis of variance, M: Mean, SD: Standard Deviation, Min: Minimum, Max.: Maximum

The mean age of the patients was 65.95±5.64 (min. 60, max. 82) years and the most common cancer types were breast (31.0%), lung (14.9%), colorectal (9.2%), prostate (5.8%), and stomach (5.8%), respectively. The patients received chemotherapy treatment (98.9%), radiotherapy (27.6%), and immunotherapy treatments (3.4%) (Table 2).

Table 2. Clinical characteristics of participants (n=174).

Type of Cancer	**n**	**%**
Breast	54	31.0
Lung	26	14.9
Colorectal	16	9.2
Prostate	10	5.8
Stomach	10	5.8
Thyroid	2	1.1
Others*	56	32.2
Chemotherapy treatment	**n**	**%**
Yes	172	98.9
No	2	1.1
Radiotherapy treatment	**n**	**%**
Yes	48	27.6
No	126	72.4
Immunotherapy treatment	**n**	**%**
Yes	6	3.4
No	168	96.6

M: Mean, SD: Standard Deviation, Min: Minimum, Max.: Maximum, * Soft tissue, lymphoma, bone, ovary, gallbladder, bladder, leukemia, uterus, skin, multiple myeloma, pancreas, kidney, liver

The majority (71.8%) of the older patients with cancer had poor sleep quality (Table 3). According to the mean scores of the scales, the patients were found to have moderate spiritual care needs (62.98±13.18) and poor sleep quality (8.14±4.81). Additionally, no significant correlation (r= -0.026; p=0.733) was found between spiritual care needs and sleep quality in older patients with cancer (Table 4).

Table 3. Sleep quality and spiritual care levels of participants (n=174).

		Spiritual Care Needs Inventory			
		Low needs	**High needs**	**Total (n)**	**Total (%)**
Pittsburgh Sleep Quality Index	**Good sleep quality**	22	27	49	28.2
	Poor sleep quality	61	64	125	71.8
	Total (n)	83	91	174	-
	Total (%)	47.7	52.3	-	100

Table 4. Relation between spiritual care need and sleep quality in older patients with cancer.

Scales	M±SD	Median (Min-Max)	Correlation analysis
Spiritual Care Needs Inventory	62.98±13.18	65 (21-98)	r: -0.026; p: 0.733
Pittsburgh Sleep Quality Index	8.14±4.81	8 (0-21)	

Pearson Correlation, M:Mean, SD: Standard Deviation, Min: Minimum, Max.: Maximum

DISCUSSION

In the present study, more spiritual care needs were found among married patients compared with those who were single, those who never used caffeine, those who used traditional treatment, and patients who could not perform religious activities during the cancer process. It is thought that married older patients with cancer have more spiritual needs because they give meaning to both themselves and their spouses in terms of life, existence, and hope. Caffeine provides positive emotions such as peace, joy, and energy, thus it is thought that patients who have never used caffeine have more spiritual care needs because they do not experience these positive emotions through caffeine use. Patients may prefer to use traditional treatment because they are looking for spiritual care content such as increasing hope, reducing stress, and accelerating healing, in addition

to treatment. It is thought that those who cannot perform religious activities due to symptoms during the cancer process need spiritual care and may need this care more than ever.

No study has been found in the literature examining the relationship between the sleep quality characteristics of older patients with cancer with similar population characteristics. The study found that the sleep quality of patients with additional chronic diseases was worse than those without. It is thought that the sleep quality of older patients with cancer with additional chronic diseases is negatively affected due to polypharmacy and its adverse effects. It is predicted that regular sleep is difficult for such patients owing to the challenge of coping with the symptoms of many chronic diseases. For this reason, it is recommended to evaluate the sleep quality of older patients with cancer with additional chronic diseases.

The average age of patients with cancer in the present study was 65.95±5.64 years and the most common cancer types were breast, lung, colorectal, prostate, and stomach, respectively. Similar to our findings, according to the World Health Organization's GLOBACAN (Global Cancer Observatory) 2020 data, it was reported that the most common cancer types experienced by individuals aged 60 years and over worldwide were lung, colorectal, prostate, breast, and stomach, respectively (World Health Organization, 2024). Even though the order was different, the same types of cancers were seen. It is thought that the reason for the difference in frequencies is due to culturally specific lifestyle differences. In addition, because breast cancer is most common in women and women are more cancer aware in this regard, it is normal for the hospital admission rate to be high in this type of cancer. Furthermore, the fact that the study group was predominantly female (60.3%) may also have had an effect.

In the study, it was determined that the majority of older patients with cancer had medium-level spiritual care needs. Similar to our results, a study found that 97.8% of patients with cancer, 73.8% of whom were aged 50 years or older, reported that they needed spiritual care. In addition, it was reported that pain and family concerns decreased significantly by 0.33 times and family concerns by 3.43 times when those who had previously received spiritual care in end-of-life care continued their care. It was reported that the anxiety of those who did not receive spiritual care decreased after receiving this care (Ratshikana-Moloko et al., 2020). In another study, it was reported that almost all older patients with cancer, 40% of whom were aged over 65 years, had spiritual needs (91%). It was also stated that patients with cancer who received less spiritual care than desired had 1.20 times higher depressive symptoms and 2.37 times lower levels of meaning and peace (Pearce et al., 2012). In the NCCN "Older Adult Oncology" version 1.2023 guideline, it was emphasized that providing spiritual care as social support to older patients with cancer and their families reduced stress, anxiety, and depression psychosocially (National Comprehensive Cancer Network, 2024). It is recommended to determine the spiritual needs of older patients with cancer according to their values and beliefs. Older patients with cancer should be supported to receive spiritual care through methods such as giving meaning to life, existential well-being, positive thinking, having a positive attitude towards life, receiving and giving love, prayer, and worship (Palmer Kelly et al., 2022).

Sleep disorders are common in older patients with cancer (Pang et al., 2019). In a prevalence study, it was stated that the rate of sleep disorders in older patients with cancer was 40%. Additionally, 39.6% of older patients with cancer experienced sleep disturbance (Loh et al., 2017). Another study stated that the prevalence of sleep disorders in patients with cancer aged 65 years and over who were treated in the hospital was 60% (Cheng & Lee, 2011). In another study, the prevalence of sleep disorders in patients with cancer was reported as 58.6% between the ages of 60-69 years and 43.8% between the ages of 70-79 years (Al Maqbali et al., 2022).

The majority of older patients with cancer had poor sleep quality in our study, and this was similarly reported by Zhang et al. (2023). In one study, it was reported that 89.7% of patients with cancer aged over 65 years had poor sleep quality. It has been reported that sleep quality worsens by 1.04 times with aging (Endeshaw et al., 2022). Disturbances in sleep patterns may occur due to a decrease in melatonin levels due to age-related degenerative changes in the suprachiasmatic nucleus in the hypothalamus. In the NCCN "Older Adult Oncology" version 1.2023 guideline, it is recommended that benzodiazepines or other sedative-hypnotics should not be used as first-line treatment for sleep disorders in older patients with cancer, and that non-pharmacologic methods such as cognitive behavioral therapy and lifestyle changes should be preferred (National Comprehensive Cancer Network, 2024). In this sense, patients' sleep quality should be improved through methods such as sleep hygiene education, distraction, reflexology, and music therapy.

No significant relationship was found between spiritual care needs and sleep quality in older patients with cancer in our study. Different from our results, it was reported that 88.9% of patients with cancer aged between 65 and 84 years experienced sleep disturbances, and 85.4% of those aged 85 years and over experienced sleep disturbances. It was also stated that they experienced stress, called spiritual pain, at a rate of 36.1% in those aged 65-84 years and in 26.3% of those aged 85 years and over (Cheng & Lee, 2011). In another study performed to determine the symptom severity of older patients with cancer with an average age of 60 years, it was reported that

these patients experienced the most severe sleep disturbance and that increasing spiritual well-being significantly reduced the severity of all symptoms by 3.29 times (Wang & Lin, 2016). These studies were not conducted on specific older patients with cancer, rather they were performed to determine sleep disorders and spiritual care needs. Additionally, these studies did not evaluate the relationship between patients' sleep quality and spiritual care needs. Meeting the spiritual care needs of older patients with cancer can help them relax by reducing stress and depression (Kutlu et al., 2011), but improving sleep quality may not always be a direct result of this process. This is because patients' sleep quality can be affected by many different factors and may not improve immediately by simply reducing stress and depression.

Limitations

Among cancer types, only primary cancer types were considered, and metastases were not taken into account. The research was not homogeneous because there were different types of cancer. Future studies may ensure a homogeneous distribution of groups by stratifying cancer types. The research data pertains only to this sample group and cannot be generalized to all older patients with cancer. The research data were collected based on patients' self-reports.

CONCLUSION

No significant relationship was found between spiritual care needs and sleep quality in older patients with cancer. However, the majority of the patients had poor sleep quality and, according to the scale score averages, moderate spiritual care needs. In addition, it was found that the spiritual care needs were higher in patients who were married, those who never used caffeine, those who used traditional treatment, and patients who could not fulfill their religious activities during the cancer process. At the same time, it was determined that among these patients, those with additional chronic diseases had poor sleep quality. It is recommended to increase specific studies on older patients with cancer and evaluate their spiritual care needs and sleep quality. It is recommended that the spiritual care needs of older patients with cancer be met on a patient-specific basis, with guidance. At the same time, training should be given to improve the sleep quality of these patients, and non-pharmacologic methods should be taught to patients and their families.

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Conflict of Interest

The authors have no conflicts to report.

Author Contributions

Plan, design: AU, FZG; **Material, methods:** AU, FZG; **Data collection:** AU; **Data analysis and comments:** AU, FZG; **Writing and corrections:** AU, FZG.

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Ethical Approval

Institution: Clinical Research Ethics Committee
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