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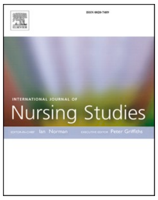

The effect of nurse-led enhanced supportive care as an early primary palliative care approach for patients with advanced cancer: A randomized controlled trial

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ABSTRACT

Background: Nurses play an important role in providing palliative care. However, few studies have evaluated the effectiveness of nurse-led primary palliative care.

Objective: To evaluate the effect of nurse-led enhanced supportive care as an early primary palliative care approach for advanced cancer patients.

Design: Randomized controlled trial.

Setting(s): This study was conducted at Yonsei Cancer Center in Seoul, Korea.

Participants: Advanced cancer patients initiating palliative chemotherapy ($N = 258$) and their family caregivers ($N = 120$) were enrolled and completed 3-month ($n = 182$ patients, $n = 79$ caregivers) and 6-month ($n = 141$ patients, $n = 60$ caregivers) follow-up assessments.

Methods: Participants were randomly assigned to the intervention or control group (1:1). The intervention group received nurse-led enhanced supportive care, which included symptom management and coping enhancement counseling before each chemotherapy cycle (baseline to 3 months) and was delivered by trained nurses. The control group received symptom monitoring. Family caregivers only participated in the evaluation. The primary outcomes were quality of life (EORTC-QLQ C30), symptoms (ESAS), and coping (Brief COPE) at 3 months. The secondary outcomes were quality of life, symptoms, and coping at 6 months. Self-efficacy for coping with cancer (CBI-3.0 K), and depression among cancer patients and family caregivers (HADS-D) at 3 and 6 months were also evaluated. The data were analyzed using linear mixed models.

Results: The intervention group reported beneficial effects in the following outcomes: 1) Quality of life [role functioning domain at 3 months (1.01 ± 2.34 vs. -8.37 ± 2.07; $p = .003$ [-15.57, -3.18]; adjusted $p = .044$), 2) coping [active coping at 3 months (0.27 ± 0.16 vs. -0.34 ± 0.14; $p = .006$ [-1.04, -0.18]; adjusted $p = .044$), and self-distraction (0.22 ± 0.17 vs. -0.42 ± 0.15; $p = .004$ [-1.08, -0.20]; adjusted $p = .044$) at 3 months]; 3) self-efficacy in coping with cancer [maintaining activity and independence at 3 months (1.45 ± 0.47 vs. -0.31 ± 0.42; $p = .006$ [-2.99, -0.52]; adjusted $p = .044$)]. The intervention was not effective in reducing symptoms and depression of patients or depression of caregivers (adjusted $p > .05$).

Conclusions: Nurse-led enhanced supportive care as an early primary palliative care approach has demonstrated effectiveness in improving the role functioning domain of quality of life, use of coping strategies, and self-efficacy in maintaining activity and independence among advanced cancer patients. Nurse-led early primary palliative care should be delivered by trained nurses and incorporated into routine oncology practice.

Registration: Registered at ClinicalTrials.gov, NCT04407013, on May 29, 2020, https://www.clinicaltrials.gov/ct2/show/study/NCT04407013. The protocol version is ESC 1.0.

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Tweetable abstract: The integration of nurse-led early primary palliative care into routine oncology practice for patients with advanced cancer is recommended.

What is already known

- Early palliative care is recommended to improve quality of life among patients with advanced cancer.
- The role of primary oncology care is emphasized in providing early palliative care.
- No study has evaluated the effect of a nurse-led early primary palliative care intervention that focuses on symptom management and coping enhancement.

What this paper adds

- The integration of nurse-led early primary palliative care into oncology practice was shown to be effective.
- Nurse-led enhanced supportive care as an early primary palliative care approach improved the role functioning domain of quality of life, use of coping strategies, and self-efficacy in maintaining activity and independence among patients with advanced cancer.
- The integration of nurse-led early primary palliative care into routine oncology practice for patients with advanced cancer is recommended.

1. Background

Advanced cancer is difficult to treat and has a poor prognosis, thus significantly reducing patients' quality of life (QoL) (Versluis et al., 2024). Palliative care addresses complex issues faced by patients with advanced cancer and improves QoL (Dans et al., 2021; Ferrell et al., 2017; Sanders et al., 2024).

The benefits of early palliative care (i.e., provided within 8 weeks after diagnosis of advanced cancer) have been reported (Temel et al., 2010). Multiple studies have subsequently demonstrated the effectiveness of early palliative care in improving QoL (Greer et al., 2022; Temel et al., 2017, 2024; Zimmermann et al., 2014), symptom management (Haun et al., 2017; Zimmermann et al., 2014), and coping (Greer et al., 2020). Current clinical guidelines recommend providing early palliative care to patients with advanced cancer (National Comprehensive Cancer Network, 2022; Sanders et al., 2024) and integrating this care with standard oncology (Greer et al., 2013). However, specialist palliative care has not been readily accessible in many clinical settings.

Primary palliative care was introduced as a way to deliver early palliative care (Hui and Bruera, 2015) and refers to palliative care provided to patients receiving cancer treatments by oncology health care providers who are not palliative care specialists (Quill and Abernethy, 2013). The key components of early palliative care include symptom management and helping individuals cope with advanced disease (Greer et al., 2020), which correspond to the roles of oncology care providers, including physicians, nurse practitioners, and nurses.

Nurses are members of multidisciplinary teams for oncology practice and for palliative care. The role of nurses in primary palliative care has not been clearly defined. Even after a position statement stating that nurses need to take an important role in providing palliative care was issued (American Nurses Association Professional Issues Panel, 2017), only a limited number of studies have developed and evaluated the effects of nursing interventions for primary palliative care (Reinke et al., 2022; Schenker et al., 2021).

Nursing interventions for primary palliative care could be developed on the basis of the key components of early palliative care, i.e., symptom management and coping counseling. The effect of symptom management has been demonstrated in multiple studies. The effects of symptom management include improving QoL (Basch et al., 2022; Maguire et al., 2021) and decreasing symptom burden (Basch et al., 2022; Huang et al., 2019; Maguire et al., 2021). Coping with advanced cancer is challenging. Every individual has their own coping mechanisms (Lazarus and Folkman, 1984). Coping strategies such as active coping, positive reframing, acceptance, and emotional support are known to be closely associated with cancer patients' quality of life (Beesley et al., 2018; Greer et al., 2018; Nipp et al., 2016). The utilization of effective coping strategies follows the mastery enhancement principle, which is known as the source of self-efficacy in social cognitive theory (Bandura, 1997). If a person's coping repertoire is limited, broadening it may be helpful (Greer et al., 2020). Acceptance and commitment therapy (ACT), known as third-wave cognitive behavioral therapy (CBT) (Hayes et al., 2012), could contribute to broadening the coping repertoire. Unlike previous CBTs, which help people manage problems by changing unhelpful thoughts and behaviors (Beck, 1993), ACT helps increase psychological flexibility to accept uncomfortable thoughts and emotions and seek true value in life (Hayes et al., 2012; Thoma et al., 2015).

Enhancing self-efficacy through mastery enhancement using previously effective coping strategies and helping expand coping strategies could contribute to effective coping in patients with advanced cancer.

With a strong emphasis on integrating early palliative care into routine oncology practice, the current study examined the effect of nurse-led enhanced supportive care as an early primary palliative care approach. Nurse-led enhanced supportive care was introduced when advanced cancer patients started their 1st-line palliative chemotherapy and were provided for 3 months, with a focus on symptom management and coping enhancement. Nurse-led enhanced supportive care was delivered by trained research nurses, i.e., experienced oncology nurses who were trained in symptom management and coping enhancement counseling.

The aim of the current study was to evaluate the effects of nurse-led enhanced supportive care on primary outcomes (including advanced cancer patients' QoL, symptoms, and coping at 3 months) and secondary outcomes (including advanced cancer patients' QoL, symptoms, and coping at 6 months; self-efficacy for coping with cancer and depression in patients at 3 and 6 months; and depression among caregivers at 3 and 6 months). The protocol of the current study was published previously (Choi et al., 2022), and the study was registered at ClinicalTrials.gov (NCT04407013).

2. Methods

2.1. Design

This study was a two-arm, nonblinded, randomized controlled trial.

2.2. Participants

Adults with advanced cancer and their family caregivers were recruited for the study. The inclusion criteria for patients were as follows: 1) were diagnosed with any type of advanced cancer (stage 3b or stage 4) and were offered palliative chemotherapy as the treatment choice; 2) were scheduled to begin their first cycle of first-line palliative chemotherapy; and 3) had an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or lower. Patients were excluded if they 1) had cognitive problems such as a diagnosis of dementia or psychiatric problems such as major depression or generalized anxiety or 2) were actively receiving treatment for any of these conditions.

2.3. Procedure

Patients and their caregivers who visited oncology outpatient clinics at a tertiary hospital in Seoul, South Korea, were approached by research nurses, who explained the study and recruited participants. Once patients provided signed informed consent, research nurses randomly allocated patients to the intervention group or the control group at a 1:1 ratio according to the randomization sequence. The randomization sequence was developed by the principal investigator (PI) using IBM SPSS 26.0 prior to participant enrollment. The participants were randomized according to cancer type, age, and sex via stratified permuted block randomization. To ensure balanced group allocation, participants were enrolled via the minimization method once 60 % enrollment in each group was reached. After random assignment, all participants in both the intervention and control groups completed the baseline assessment (T1). At this point, none of the participants were informed of their group allocation. All participants completed self-reported responses, while trained research nurses provided assistance as needed to ensure accurate understanding of the questions without influencing participant responses, thereby maintaining objectivity throughout the process. Following the baseline assessment, blinding participants was no longer maintained due to the nature of the intervention. Patients in both the intervention and control groups participated in symptom monitoring from T1-T5, which corresponds to hospital visits for the chemotherapy infusion cycle. The intervention group patients received nurse-led enhanced supportive care (symptom management and coping enhancement counseling sessions) from trained research nurses (T1-T5). At 3 months (T5) and 6 months (T6), patients in both groups of patients completed the same questionnaires as at baseline. The study was not blinded because of the nature of the intervention. The research nurses received thorough training in how to perform their roles in the data collection process without introducing bias given their awareness of the group allocation after random assignment.

2.4. Study intervention

The intervention group patients received enhanced supportive care, which was developed as a nursing intervention aimed at providing early palliative care through trained nurses. The nurse-led enhanced supportive care intervention was developed by integrating two key elements of early palliative care: symptom management and coping enhancement (Hoerger et al., 2018; Jacobsen et al., 2011). Symptom management includes symptom monitoring and evidence-based symptom management education (Basch et al., 2022; Maguire et al., 2021). To help individuals cope with advanced disease, self-efficacy for coping with cancer has improved through mastery enhancement (Chirico et al., 2017; Nairn and Merluzzi, 2019; Zhang et al., 2014), and ACT has been introduced to improve psychological flexibility as a new way of coping (Arch et al., 2020; Rost et al., 2012). The specific details of the intervention are presented in the protocol paper (Choi et al., 2022).

The intervention consisted of five sessions (both symptom management and coping enhancement counseling sessions). The intervention group participated in symptom monitoring via tablets. Current symptom assessments were compared with previous monitoring results to track changes over time, with visual feedback provided through graphs. Depending on the symptom issues identified through symptom monitoring, face-to-face evidence-based symptom management education using tablets and booklets was provided, including the use of prescribed medication and nonpharmacological strategies such as deep breathing and relaxation techniques. This approach aimed to empower patients to manage their symptoms effectively between sessions. Face-to-face sessions provided counseling for coping enhancement. Coping enhancement counseling was developed on the basis of self-efficacy in social cognitive theory and the ACT. Patients were encouraged to identify and utilize their own effective coping strategies and to identify thoughts and emotions while pursuing personal values and performing committed actions. The counseling sessions had specific themes for each session: 1) introduction to coping enhancement counseling, 2) identifying patients' emotions and coping strategies, 3) finding values in life, 4) committing to life values, and 5) reviewing the sessions to promote the use of effective coping strategies, accept emotions and thoughts, and commit to life values (Choi et al., 2022). Coping enhancement counseling involved content that had to be built on the basis of previously discussed content. An intervention session was delivered during each clinic visit for chemotherapy infusion (1 session for each hospital visit*5 times). Each session lasted approximately 45 min (44.2 ± 8.6, range: 10–69), with the first 15 min dedicated to symptom management (15.2 ± 5.0, range: 2–31) and the remaining 30 min dedicated to coping enhancement counseling (29.0 ± 5.8, range: 6–45).

The control group participated in symptom monitoring only across five visits (T1-T5), i.e., symptom assessments via tablets at each visit without additional education or counseling. Caregivers only participated in the evaluation. Data were collected at baseline (T1), at each chemotherapy cycle (only patients at T2-T4), at 3 months (T5), and at 6 months (T6).

Research nurses were initially trained on coping enhancement counseling by a certified clinical psychologist (one of the authors, S.C.) through didactic sessions (5 sessions for 3 days). The nurses also participated in role-playing sessions by taking turns as patient and counselor. The training aimed to reinforce the research nurses' understanding of counseling, increase their knowledge of the self-efficacy of social cognitive theory and the ACT approach, and develop counseling skills. Three research nurses were trained and supervised by the PI and a certified clinical psychologist (S.C.). They also participated in three consulting sessions and a refresher training session and attended basic and advanced level ACT workshops.

2.5. Measurements

Quality of life among cancer patients was measured using the EORTC QLQ-C30 (Yun et al., 2004), which includes 5 functional subscales (physical, role, emotional, cognitive, and social) and a global health status/QoL subscale. The items were rated on a 4-point scale, except for two items for the global health status/QoL subscale, which were scored on a 7-point scale. Subscale scores were standardized and ranged from 0 to 100. The Cronbach's alpha coefficients of the subscales ranged from 0.60 to 0.87 in the Korean validation study and from 0.50 to 0.86 in the current study.

Symptoms were measured using the Edmonton Symptom Assessment Scale (ESAS) (Kwon et al., 2013). Additional symptoms that were measured herein included cognition, constipation, diarrhea, peripheral neuropathy (Reeve et al., 2014), and vomiting. The participants rated their symptoms on an 11-point scale (0 = not at all and 10 = most intense). The Cronbach's alpha coefficient of the Korean version of the ESAS in the validation study was 0.88 (Kwon et al., 2013), and it was 0.86 in the current study. The Cronbach's alpha coefficient of the ESAS with 15 symptoms in the current study was 0.85.

Coping was evaluated using a simplified version of the Coping Orientation to Problems Experienced (Brief COPE) inventory (Carver, 1997), which includes 28 items that assess 14 coping strategies on a 4-point scale: 1) self-distraction, 2) active coping, 3) denial, 4) substance use, 5) use of emotional support, 6) use of instrument support, 7) behavioral disengagement, 8) venting, 9) positive reframing, 10) planning, 11) humor, 12) acceptance, 13) religion, and 14) self-blame. A higher score indicates greater utilization of the coping strategy. The Cronbach's alpha coefficients ranged from 0.50 to 0.90 in the study by Dev et al. (2024) and from 0.53 to 0.90 in the current study, except for self-distraction (0.49), behavioral disengagement (0.48), humor (0.44), and the use of emotional support (0.12).

Self-efficacy for coping with cancer was assessed using the Cancer Behavior Inventory (CBI) version 3.0-Korean (CBI 3.0-K) (Lee et al., 2021), which includes 27 items across 7 subscales: 1) maintaining activity and independence, 2) seeking and understanding medical information, 3) managing stress and distress, 4) managing side effects, 5) accepting cancer/maintaining a positive attitude/making decisions, 6) seeking support, and 7) using spiritual coping. The items were scored on a 7-point Likert scale. The Cronbach's alpha coefficients for this instrument ranged from 0.86 to 0.97 in the Korean version of the instrument validation study (Lee et al., 2021) and from 0.84 to 0.97 in the current study.

Depression in patients and caregivers was assessed using the depression subscale of the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983). There were 7 items each for depression (HADS-D), and each item was scored on a 4-point scale (0–3). Higher scores indicate higher levels of depression. The Cronbach's alpha coefficient of the Korean version of the HADS-D was 0.75 in the study by Kim et al. (2017). In the current study, the Cronbach's alpha coefficient was 0.75 for the HADS-D.

Basic sociodemographic information, including age, sex, economic level, educational level, marital status, and religion, as well as disease characteristics, such as cancer type and stage, were collected using standardized questionnaires designed specifically for the current study. The ECOG performance status was used to assess functional status, with scores ranging from 0 to 4. A higher score indicates a greater decline in performance (Oken et al., 1982).

2.6. *Analysis*

The sample size for the linear mixed model (LMM) used for two-group differences at two time points was estimated to be 70 on the basis of $\alpha = 0.05$, power = 0.80, and a moderate effect size *of* partial eta squared $\eta^2 = 0.06$ (two-sided) (Cohen, 1988). The study featured three primary endpoints, and the power pertaining to each primary endpoint was set as 0.93; the final power was determined to be 0.80 ($0.93 \times 0.93 \times 0.93 = 0.80$). The correlations among the repeated measures were set as 0.30. The effect size was estimated on the basis of previous early palliative care studies, which reported small to moderate effects for symptoms (Bakitas et al., 2015; Temel et al., 2010; Zimmermann et al., 2014), moderate effects for coping (Greer et al., 2018), and moderate effects for QoL (Temel et al., 2010; Vanbutsele et al., 2018). Given the use of structural equation modeling to analyze the relationships among the variables under investigation in this research, more than 300 participants were recommended. Furthermore, given the longitudinal data collection and a dropout rate of 20 %, this research aimed to recruit a total of 360 participants (i.e., patients with advanced cancer and their family caregivers) (Choi et al., 2022).

A total of 512 cancer patients were screened, and 258 (50.4 %) agreed to participate and be enrolled. Not all enrolled patients were accompanied by their family caregivers. We were able to screen 161 family caregivers who accompanied patients during their hospital visit, and 120 family caregivers agreed to participate and enroll (74.5 %). When patients withdrew from the study, their caregivers were also excluded.

A per-protocol analysis was conducted to reflect the consecutive nature of the intervention. Complete data were utilized for the analysis of outcomes from T1 to T5 (considering the nature of the intervention: previous symptom monitoring data were used as a reference for symptom change, and each session of coping enhancement counseling was built upon discussions in the previous session). Missing data exist in the T6 data. Descriptive statistics were used to summarize the data. A *linear mixed model* (LMM) was applied to examine differences in changes from baseline to each data collection point by group, time, and group by time, considering the baseline score as a covariate. The model was estimated using the restricted maximum likelihood (REML). The assumptions for LMM, such as normality, independence, and homoscedasticity of residuals, were checked. This study had three primary outcomes. The measurement instruments for QoL, coping, and self-efficacy for coping with cancer were developed and validated as having multiple domains and did not suggest the use of total scores. We considered each domain score as an outcome variable. In an effort to address multiple testing issues, the Benjamini-Hochberg procedure was applied to all outcomes at each time point (Benjamini and Hochberg, 1995). IBM SPSS (version 27, IBM Corp., Armonk, NY, USA) was used for data analysis.

2.7. *Ethics approval and informed consent*

The current study was conducted in accordance with the ethical standards presented in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The institutional review board of the Yonsei University Health System approved the study (4-2020-0304). Research nurses explained the purpose and procedure of the study to cancer patients and their family caregivers, and written informed consent was obtained.

2.8. *Trial registration*

Registered at ClinicalTrials.gov, NCT04407013 on May 29, 2020, https://classic.clinicaltrials.gov/ct2/show/NCT04407013.

The protocol version is ESC 1.0.

3. Results

3.1. *General characteristics (N = 258)*

The participants were recruited from March 22, 2021, to November 21, 2023, and the final data collection was completed on February 28, 2024, marking the end of the planned research period (Fig. 1).

The participants in the current study were middle-aged and were mostly diagnosed with breast, colorectal, hepatobiliary/pancreatic, lung, or stomach cancer. Slightly more than half of the participants had an ECOG performance status of 0, indicating no functional limitations. No differences in demographic characteristics were found between the intervention and control groups (Table 1). Advanced cancer patients who completed the 3-month data collection were significantly younger than those who dropped out (56.8 ± 12.0 vs. 61.2 ± 11.6; p = .008). No other differences were observed between those who completed data collection and those who dropped out (Supplementary Table 1). None of the patient participants reported adverse events related to the study.

The caregivers who participated in the study were primarily middle-aged; over half of them were female and spouses of the patients. No differences in the demographic characteristics of the caregivers were found between the intervention and control groups (Supplementary Table 2). None of the caregivers reported adverse events related to the study.

3.2. *Primary endpoint*

3.2.1. *QoL at 3 months*

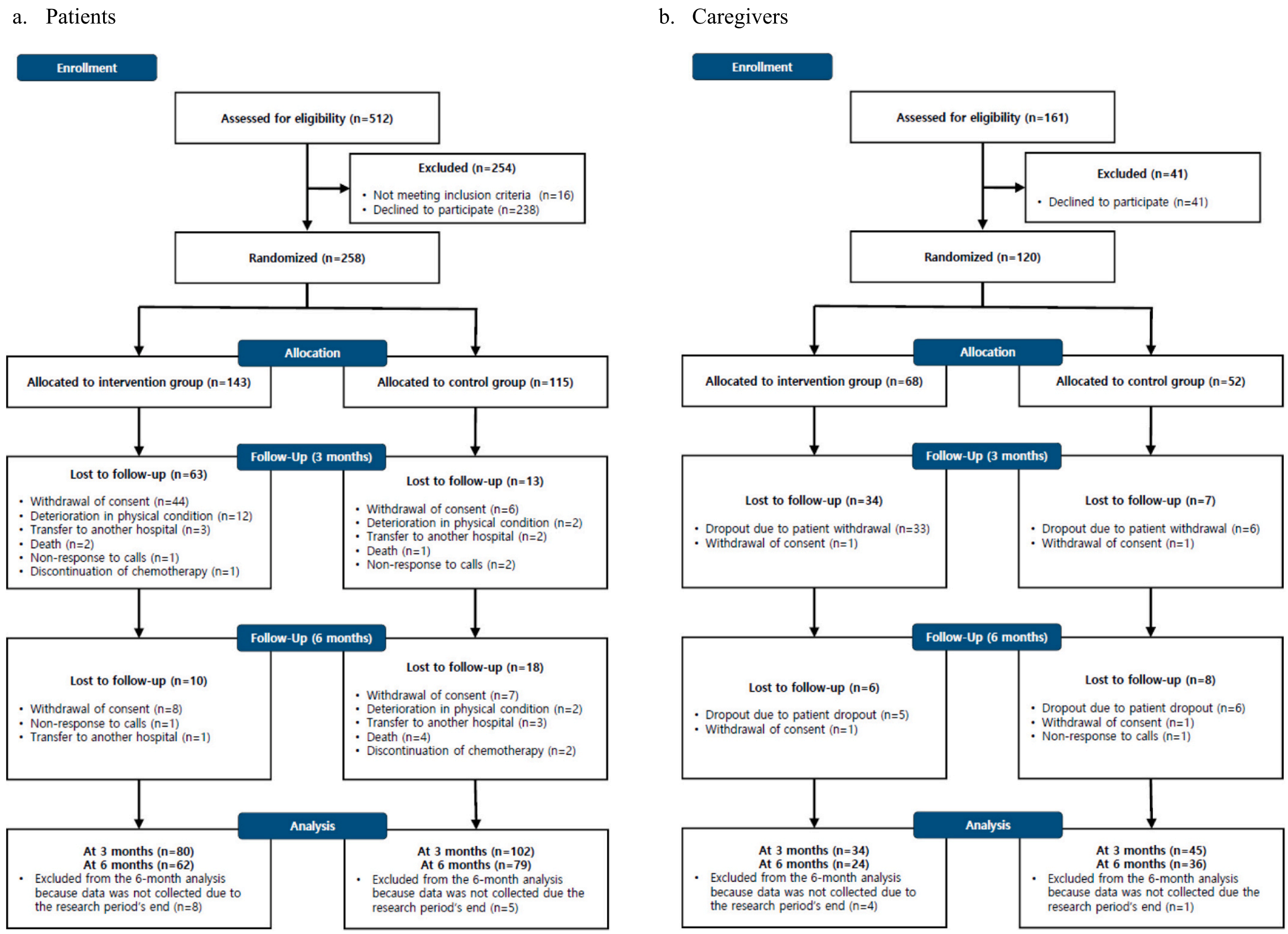
Among the QoL subscales, a statistically significant between-group difference was observed in the change in role functioning from baseline to 3 months ($t = -2.99$; $p = .003$ [-15.57, -3.18]; adjusted $p = .044$).

3.2.2. *Symptoms at 3 months*

No statistically significant between-group difference was observed in symptoms from baseline to 3 months ($t = -0.17$; $p = .865$ [-4.60, 3.87]; adjusted $p = .865$).

3.2.3. *Coping at 3 months*

Among the coping subscales, a statistically significant between-group difference was observed in the changes in self-distraction ($t = -2.89$; $p = .004$ [-1.08, -0.20]; adjusted $p = .044$) and active coping ($t = -2.80$; $p = .006$ [-1.04, -0.18]; adjusted $p = .044$) from baseline to 3 months (Tables 2, 3).


a. Patients

b. Caregivers

Fig. 1. CONSORT flow diagram.

3.3. *Secondary outcomes*

3.3.1. *QoL at 6 months*

No statistically significant between-group differences were observed in the QoL subscales from baseline to 6 months (adjusted $p > .05$).

3.3.2. *Symptoms at 6 months*

No statistically significant between-group difference was observed in symptoms from baseline to 6 months ($t = -0.01$; $p = .993$ [−5.49, 5.44]; adjusted $p = .993$).

3.3.3. *Coping at 6 months*

No statistically significant between-group differences were observed in the scores of the coping subscales from baseline to 6 months (adjusted $p > .05$) (Table 2, Supplementary Table 3).

3.3.4. *Self-efficacy for coping with cancer at 3 months and 6 months*

Among the self-efficacy subscales, a statistically significant between-group difference was observed in the changes in maintaining activity and independence ($t = -2.79$; $p = .006$ [−2.99, −0.52]; adjusted $p = .044$) from baseline to 3 months. No statistically significant between-group difference was observed in self-efficacy for coping with cancer subscales from baseline to 6 months (adjusted $p > .05$).

3.3.5. *Depression at 3 months, 6 months*

No statistically significant between-group differences were observed in depression from baseline to 3 months ($t = 1.90$; $p = .059$ [−0.04, 1.99]; adjusted $p = .190$) or from baseline to 6 months ($t = 2.03$; $p = .044$ [0.03, 2.31]; adjusted $p = .319$).

3.3.6. *Depression of family caregivers at 3 months and 6 months*

No statistically significant between-group differences were observed in the depression of family caregivers from baseline to 3 months ($t = 0.89$; $p = .379$ [−0.84, 2.18]) or from baseline to 6 months ($t = -1.12$; $p = .266$ [−2.45, 0.69]) (Tables 2, 3, Supplementary Table 3).

4. Discussion

4.1. *QoL*

The nurse-led enhanced supportive care evaluated in the current study did not effectively improve overall QoL, which was measured via general health/QoL domain of the EORTC QLQ-C30. Studies that have investigated early palliative care have reported benefits pertaining to overall QoL at 12 weeks (Temel 2010; Temel et al., 2017; Vanbutsele et al., 2018), 18 weeks (Kang et al., 2024; Vanbutsele et al., 2018), and 24 weeks (Temel et al., 2017), although early palliative care trials targeting gastrointestinal cancer patients failed to achieve the expected outcomes (Temel et al., 2017; Adenis et al., 2024). Early palliative care interventions that had positive effects were provided on a monthly basis by a multidisciplinary team until patients' death. Nurses play important roles in this context as multidisciplinary team members; however, the effects reported in nurse-led palliative care trials with respect to improvements in QoL have been inconsistent (Reinke et al., 2022; Schenker

Table 1
General characteristics of participating patients and a comparison between the intervention and control groups (N = 258).

Characteristic	Group, M ± SD or N (%)		t or X^2	p-Value
	Intervention (n = 143)	Control (n = 115)		
Age	59.1 ± 11.9	56.9 ± 12.2	1.48	.141
Sex			1.10	.295
Male	79 (55.24 %)	56 (48.70 %)		
Female	64 (44.76 %)	59 (51.30 %)		
Diagnosis			4.47	.484
Breast cancer	15 (10.49 %)	17 (14.78 %)		
Colorectal cancer	21 (14.69 %)	18 (15.65 %)		
Liver/gallbladder/pancreatic cancer	40 (27.97 %)	22 (19.13 %)		
Lung cancer	34 (23.78 %)	24 (20.87 %)		
Stomach cancer	17 (11.89 %)	16 (13.91 %)		
Other cancer	16 (11.19 %)	18 (15.65 %)		
Stage			0.60	.439
3b	1 (0.70 %)	2 (1.74 %)		
4	142 (99.30 %)	113 (98.26 %)		
ECOG PS			0.01	.924
0	75 (52.45 %)	61 (53.04 %)		
1	68 (47.55 %)	54 (47.96 %)		
Comorbid disease			0.01	.924
Yes	75 (52.45 %)	61 (53.04 %)		
No	68 (47.55 %)	54 (46.96 %)		
Educational level			4.10	.043
Up to high school	84 (58.74 %)	53 (46.09 %)		
College or above	59 (41.26 %)	62 (53.91 %)		
Income (monthly)			2.24	.134
< 3,000,000 won	60 (41.96 %)	59 (51.30 %)		
≥ 3,000,000 won	83 (58.04 %)	56 (48.70 %)		
Marital status			0.26	.612
Married	112 (78.32 %)	87 (75.65 %)		
Not married	31 (21.68 %)	28 (24.35 %)		
Religious affiliation			0.05	.816
Yes	85 (59.44 %)	70 (60.87 %)		
No	58 (40.56 %)	45 (39.13 %)		

Note. ECOG PS, Eastern Cooperative Oncology Group performance status.

et al., 2021; Vanbutsele et al., 2018). The provision of nurse-led primary palliative care by infusion room nurses over 12 weeks, including symptom management, emotional support, advance care planning and care coordination, did not improve overall QoL (Schenker et al., 2021). Nurse-led palliative care interventions consisting of baseline assessments and follow-ups with a focus on symptom management, which were implemented by trained research nurses over 12 weeks, were not reported to improve overall QoL effectively (Reinke et al., 2022). Nurse-led early primary palliative care consisting of a baseline assessment and monthly consultations until death, particularly with respect to symptom burden, psychological and spiritual coping and decision-making, resulted in improvements in overall QoL (Vanbutsele et al., 2018). The key difference in such nurse-led early primary palliative care studies, which have highlighted the benefits of this approach with respect to overall QoL, has pertained to the integration of oncology and palliative care. Weekly multidisciplinary team meetings, the integration of reports into electronic records, and necessary referrals to other health care professionals by palliative care nurses have been employed in this context. Duration of care extending more than 3 months has also represented such a difference. The nurse-led early palliative care approach make take into account both the scope of practice and the duration of care to be effective. The integration of nurse-led early primary palliative care into oncology practice, namely, as part of a multidisciplinary approach, could enhance the provision of supportive care by facilitating the proactive identification of patients' concerns and implementing appropriate interventions.

Of the five functional subscales assessed, only role functioning demonstrated a statistically significant difference at 3 months. The other subscales did not show statistically significant changes. These results highlight the selective impact of the intervention, which may reflect its specific focus on supporting patient autonomy and daily activity. The role functioning domain of QoL assesses patients' ability to perform activities associated with work or other daily activities as well as pursue their hobbies or leisure activities (Aaronson et al., 1993). Notably, the role functioning domain is one of the most commonly affected functional areas among outpatients newly diagnosed with advanced cancer, alongside overall QoL (Siemens et al., 2020). In the study conducted by Vanbutsele et al., both role functioning and overall QoL (but not other functioning domains) were associated with a beneficial effect of early integrated palliative care at both 12 weeks and 18 weeks (Vanbutsele et al., 2018). The components of nurse-led enhanced supportive care and their relationship with overall QoL according to previous studies suggest various possible interpretations of the identified benefits pertaining to role functioning, although direct comparisons may not be feasible. Monitoring symptoms and providing tailored guidance for self-management or medical contact have been reported to improve overall QoL (Absolom et al., 2021). The use of adaptive coping strategies, such as active coping, has been reported to be positively correlated with overall QoL (Nipp et al., 2016). The mediating role played by coping strategies in the relationship between self-efficacy and overall QoL among cancer patients has been demonstrated (Rammant et al., 2022). The improvement in self-efficacy with regard to maintaining activities and independence observed in the current study may help explain the positive findings pertaining to the role functioning domain of QoL. The mechanisms through which early primary palliative care contributes to the role functioning domain of QoL should be explained by further research. Although other domains did not reach statistical significance, some demonstrated trends that may still hold clinical relevance, particularly in the context of supportive care for advanced cancer patients.

4.2. Symptoms

No difference was identified in symptoms between the enhanced supportive care intervention group and the control group. The lack of difference in symptoms between the intervention and control groups might be due to both groups receiving symptom monitoring, which has been shown to have beneficial effects (Basch et al., 2022; Bryant et al., 2020). Patients with advanced cancer experience symptoms that require both self-management and pharmacological treatment (Henson et al., 2020). The relatively small effects of evidence-based symptom management education above and beyond the effects of symptom monitoring require further consideration. The evidence-based symptom management education lasted for an average of 15 min, which may not have been enough time to provide sufficient support for symptom control in advanced cancer patients. A study by Absolom et al. (2021) reported that personalized symptom monitoring and self-management advice led to improved symptom control among patients undergoing curative treatment but was not effective for patients with metastatic cancer (Absolom et al., 2021). This finding highlights the need for a comprehensive and intensive approach to symptom management in patients with advanced cancer. Another explanation could be the relatively low symptom levels of the participants in the current study, which left little room for improvement (Bakitas et al., 2009).

Providing symptom monitoring for symptom management requires the active involvement of responsible health care providers. Taking specific action to manage persistent symptoms and emergencies, such as referring patients to acute care, achieved the expected outcomes (Maguire et al., 2021). In the present study, symptom monitoring outcomes were provided to oncology physicians as a reference for practice, without control over whether the physicians used the information in their practice or took action to manage the symptoms. The absence of communication regarding identified symptom management issues among healthcare providers (Reinke et al., 2022) has resulted in positive outcomes. To ensure that symptom management interventions improve

Table 2
Quality of life, symptoms, and coping of patients at 3 months.

Variables	Groups	Time point, M ± SD		Estimated mean (SE)[a]	t	*p*-Value [95 % CI]	Adjusted *p*-value
		Baseline (n = 258)	3 months (n = 182)				
Quality of life							
Global health status/QoL[b]	IG	57.7 ± 23.6	68.6 ± 20.1	8.29 (2.31)	−1.51	.133 [−10.83, 1.44]	.297
	CG	53.9 ± 23.1	61.2 ± 23.6	3.59 (2.05)			
Physical functioning	IG	74.6 ± 21.1	77.0 ± 16.1	−0.83 (1.88)	−1.83	.069 [−9.59, 0.36]	.200
	CG	72.8 ± 19.1	70.1 ± 20.0	−5.45 (1.66)			
Role functioning[c]	IG	76.8 ± 25.3	82.3 ± 20.6	1.01 (2.34)	−2.99	.003 [−15.57, 3.18]	.044
	CG	76.0 ± 26.4	70.3 ± 24.8	−8.37 (2.07)			
Emotional functioning[b]	IG	74.5 ± 23.1	85.1 ± 16.5	12.13 (1.60)	−1.55	.123 [−7.57, 0.91]	.297
	CG	67.6 ± 22.6	79.0 ± 16.4	8.79 (1.41)			
Cognitive functioning[b]	IG	85.8 ± 17.6	88.8 ± 14.9	2.53 (1.56)	−1.11	.267 [−6.43, 1.79]	.393
	CG	83.8 ± 17.8	85.3 ± 14.7	0.21 (1.38)			
Social functioning[b]	IG	70.5 ± 28.4	77.7 ± 25.3	5.96 (2.61)	−0.93	.352 [−10.15, 3.63]	.486
	CG	66.8 ± 28.5	71.7 ± 26.6	2.70 (2.31)			
Symptoms	IG	22.2 ± 17.9	15.1 ± 16.0	−5.38 (1.59)	−0.17	.865 [−4.60, 3.87]	.865
	CG	26.3 ± 18.7	17.6 ± 16.2	−5.74 (1.41)			
Coping							
Self-distraction	IG	5.4 ± 1.5	5.7 ± 1.6	0.22 (0.17)	−2.89	.004 [−1.08, −0.20]	.044
	CG	5.8 ± 1.5	5.3 ± 1.7	−0.42 (0.15)			
Active coping	IG	5.8 ± 1.5	6.2 ± 1.5	0.27 (0.16)	−2.80	.006 [−1.04, −0.18]	.044
	CG	6.2 ± 1.3	5.8 ± 1.6	−0.34 (0.14)			
Denial	IG	4.1 ± 1.7	3.5 ± 1.4	−0.58 (0.14)	0.35	.725 [−0.30, 0.42]	.785
	CG	4.1 ± 1.7	3.5 ± 1.3	−0.52 (0.12)			
Substance use	IG	3.0 ± 1.7	2.2 ± 0.8	−0.86 (0.11)	0.40	.688 [−0.23, 0.35]	.785
	CG	3.1 ± 1.8	2.3 ± 1.1	−0.80 (0.10)			
Use of emotional support	IG	4.6 ± 1.2	5.1 ± 1.3	0.12 (0.15)	−1.10	.271 [−0.62, 0.18]	.393
	CG	5.2 ± 1.4	5.0 ± 1.4	−0.10 (0.13)			
Use of instrumental support	IG	4.7 ± 1.6	4.8 ± 1.6	−0.10 (0.16)	−1.23	.221 [−0.67, 0.16]	.377
	CG	5.1 ± 1.8	4.7 ± 1.7	−0.36 (0.14)			
Behavioral disengagement	IG	3.3 ± 1.3	3.0 ± 1.1	−0.40 (0.12)	1.42	.158 [−0.09, 0.56]	.319
	CG	3.5 ± 1.3	3.2 ± 1.3	−0.16 (0.11)			
Venting	IG	4.4 ± 1.5	4.2 ± 1.5	−0.18 (0.15)	0.34	.731 [−0.33, 0.47]	.785
	CG	4.5 ± 1.4	4.3 ± 1.4	−0.11 (0.13)			
Positive reframing	IG	5.9 ± 1.5	6.2 ± 1.4	0.21 (0.14)	−1.95	.053 [−0.75, 0.005]	.190
	CG	6.2 ± 1.4	6.0 ± 1.4	−0.17 (0.13)			
Planning	IG	5.4 ± 1.5	5.2 ± 1.4	−0.44 (0.15)	0.56	.576 [−0.28, 0.50]	.721
	CG	5.7 ± 1.4	5.4 ± 1.6	−0.33 (0.13)			
Humor	IG	4.2 ± 1.4	4.5 ± 1.3	0.11 (0.15)	−1.31	.193 [−0.66, 0.13]	.350
	CG	4.5 ± 1.4	4.2 ± 1.5	−0.16 (0.13)			
Acceptance	IG	6.1 ± 1.4	6.5 ± 1.4	0.14 (0.15)	−0.53	.597 [−0.51, 0.30]	.721
	CG	6.3 ± 1.4	6.4 ± 1.5	0.03 (0.14)			
Religion	IG	4.5 ± 2.2	4.8 ± 2.2	0.29 (0.16)	−1.19	.237 [−0.66, 0.17]	.382
	CG	4.6 ± 2.2	4.6 ± 2.3	0.04 (0.14)			
Self-blame	IG	3.6 ± 1.4	3.1 ± 1.2	−0.58 (0.14)	1.39	.165 [−0.11, 0.62]	.319
	CG	3.8 ± 1.6	3.5 ± 1.4	−0.32 (0.12)			

Note. CG, control group; CI, confidence interval; IG, intervention group; QoL, quality of life; SE, standard error.

[a] Estimated mean differences (standard error) between baseline and 3 months.

[b] Missing data at baseline (n = 2).

[c] Missing data at baseline (n = 1).

patient outcomes, nurses should receive rigorous training in symptom management, and significant symptom monitoring outcomes should be communicated to responsible personnel so that they can take necessary action. The integration of symptom monitoring into electronic medical systems has not been considered necessary (Basch et al., 2022).

4.3. Coping

Nurse-led enhanced supportive care interventions involve coping enhancement counseling that aims to reinforce existing coping mechanisms and broaden patients' coping repertoire. The participants who received the intervention exhibited increased levels of active coping and increased use of self-distraction at 3 months. Among the various coping strategies, active coping is often considered an adaptive coping strategy that is often recommended (Dev et al., 2024). In a study by Greer et al. (2018), which investigated the role of coping in the effect of early palliative care on QoL, the effectiveness of approach-oriented adaptive coping strategies, including active coping as well as reframing and acceptance, was increased by early palliative care, and these strategies contributed to improved QoL.

Increased use of self-distraction requires careful interpretation because distraction is often viewed as a maladaptive coping strategy (Dev et al., 2024). However, no specific coping strategies consistently result in positive outcomes, and the use of self-distraction could be helpful in dealing with stress (Greer et al., 2020). Self-distraction, which is often considered a maladaptive strategy, may have been used to avoid becoming preoccupied with current thoughts and emotions. The items on the self-distraction subscale assess the respondent's ability to take their mind off and think less. These items may have been interpreted differently after exposure to ACT, which encouraged individuals not to focus on difficult thoughts or emotions but instead to focus on finding and seeking value.

4.4. Self-efficacy for coping with cancer

Nurse-led enhanced supportive care led to significantly greater self-efficacy in terms of maintaining activities and independence at 3 months. Monitoring symptoms and providing tailored advice led to

Table 3
Self-efficacy for coping with cancer and depression of cancer patients, and depression of caregivers at 3 months.

Variables (patients)	Groups	Time point, M ± SD		Estimated mean (SE)[a]	t	*p*-Value [95 % CI]	Adjusted *p*-value
		Baseline (n = 258)	3 months (n = 182)				
Self-efficacy for coping with cancer							
Maintaining activity and independence	IG	20.4 ± 4.9	22.0 ± 4.2	1.45 (0.47)	−2.79	.006 [−2.99, −0.52]	.044
	CG	20.2 ± 5.3	19.9 ± 5.1	−0.31 (0.42)			
Seeking and understanding medical information	IG	15.8 ± 4.0	16.5 ± 4.2	0.67 (0.43)	−0.85	.394 [−1.64, 0.65]	.519
	CG	16.3 ± 3.7	16.2 ± 3.9	0.18 (0.38)			
Managing stress and distress	IG	20.6 ± 4.7	22.0 ± 4.9	1.33 (0.50)	−1.97	.050 [−2.62, 0.002]	.190
	CG	20.7 ± 4.9	20.6 ± 5.2	0.20 (0.44)			
Managing side effects	IG	19.7 ± 5.4	21.9 ± 5.1	2.01 (0.54)	−2.35	.020 [−3.11, −0.27]	.111
	CG	19.5 ± 5.2	19.8 ± 5.5	0.33 (0.48)			
Accepting cancer/Managing a positive attitude/making decisions	IG	27.1 ± 5.7	29.1 ± 5.4	1.85 (0.58)	−2.29	.023 [−3.28, −0.24]	.111
	CG	26.9 ± 5.6	27.0 ± 5.7	0.09 (0.51)			
Seeking support	IG	13.6 ± 4.4	14.6 ± 4.7	0.62 (0.48)	−1.67	.097 [−2.32, 0.19]	.256
	CG	13.8 ± 4.4	13.4 ± 4.8	−0.45 (0.42)			
Using spiritual coping	IG	16.9 ± 8.0	17.6 ± 8.5	−0.02 (0.74)	0.19	.847 [−1.75, 2.13]	.865
	CG	17.9 ± 8.1	17.9 ± 8.1	0.17 (0.65)			
Depression	IG	7.3 ± 4.1	4.7 ± 3.7	−1.77 (0.38)	1.90	.059 [−0.04, 1.99]	.190
	CG	6.8 ± 3.8	5.8 ± 4.0	−0.80 (0.34)			

Variables (caregivers)	Groups	Time point, M ± SD		Estimated mean (SE)[a]	t	*p*-Value [95 % CI]
		Baseline (n = 120)	6 months (n = 60)			
Depression	IG	9.1 ± 4.9	7.7 ± 4.1	−1.05 (0.58)	0.89	.379 [−0.84, 2.18]
	CG	9.7 ± 4.6	8.6 ± 4.0	−0.37 (0.49)		

Note. CG, control group; CI, confidence interval; IG, intervention group; SE, standard error.

[a] Estimated mean differences (standard error) between baseline and 3 months.

increased self-efficacy in terms of symptom self-management (Absolom et al., 2021). Similarly, symptom monitoring and clinician contact in the case of a chemotherapy emergency led to improved self-efficacy in terms of symptom control by maintaining positive attitudes, understanding and participating in care, and seeking and obtaining information (Maguire et al., 2021). The mediating role of self-efficacy between symptoms and physical functional status explains how symptom control contributes to self-efficacy for maintaining activities and independence (Hoffman et al., 2009). In the present study, self-efficacy for managing side effects increased in the intervention group, but the difference was not statistically significant, and symptoms did not differ between groups. The mechanisms behind the effect of enhanced supportive care on improving self-efficacy in coping with cancer and its associated outcomes need further study.

4.5. Depression

The nurse-led enhanced supportive care approach was not effective in reducing depression among advanced cancer patients or their family caregivers. In a previous systematic review, early palliative care was not found to be effective for reducing depression (Haun et al., 2017). However, subsequent studies reported the beneficial effects of early palliative care on depression among cancer patients (Temel et al., 2017) and among family caregivers of cancer patients (El-Jawahri et al., 2017). A recent meta-analysis of palliative care interventions against psychological distress reported that palliative care involving general psychosocial support did not reduce anxiety, depression, or psychological distress in patients or caregivers (Nowels et al., 2023). Although the early palliative care approach in the current study provided structured psychological support, the outcome was consistent with that of the previous meta-analysis. Floor effects or the exclusion of individuals with mental health issues may have contributed to the null effects (Nowels et al., 2023).

4.6. Limitations

This study was conducted at a single site during the COVID-19 pandemic, which limits the generalizability of the findings. The dropout rate was quite high; however, it was similar to the rates reported in other intervention studies of patients with advanced cancer (29–35 %) (Vanbutsele et al., 2020; Zimmermann et al., 2014). An acceptable level of power was achieved with the current sample size.

Baseline data were collected after randomization and before the initiation of the interventions. None of the study participants were informed of their group assignment while they filled out the baseline questionnaires, which were self-rated patient-reported outcome measures. Standardized training and data collection procedures were employed, and the researchers maintained objectivity; however, potential bias from the researchers could not be eliminated. While the nature of the intervention made the task of blinding relevant individuals challenging, the lack of blinding represents a limitation of the study, as it may have introduced bias.

Per-protocol analysis was conducted due to dropout and the nature of the intervention. Most instruments used in the current study are composed of subscales. Establishing multiple primary outcomes requires careful consideration in terms of sample size determination and analysis. Utilizing instruments consisting of multiple domains also presents multiple testing challenges. The current study applied the Benjamini-Hochberg procedure to address this issue. However, some of the results identified as nonsignificant could have been significant findings if a single test were conducted. The results of these studies need careful interpretation and require further study.

Counseling sessions were not recorded to allow patients to share their thoughts and feelings in a comfortable setting. Periodic educational training was provided to research nurses to reinforce the principals of counseling and enhance their understanding of ACT.

However, the fidelity of coping enhancement counseling is difficult to evaluate. The use of a general coping checklist (Brief COPE) might not have been appropriate for measuring changes in coping. Some of the subscales of the Korean version of the Brief COPE demonstrated low reliability (one of the items in the use of emotional coping subscale was worded opposite to another item, which might have contributed to the low Cronbach's alpha coefficient).

5. Conclusions

Nurse-led enhanced supportive care as an early palliative care approach has beneficial effects on the role functioning domain of QoL, use of coping strategies, and self-efficacy in maintaining activity and independence among advanced cancer patients. Nurse-led early palliative care needs to be delivered by dedicated nurses who have been trained and who are assigned to provide early palliative care. Nurse-led early primary palliative care needs to be incorporated into routine oncology practice for patients with advanced cancer.

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CRediT authorship contribution statement

Yun Young Choi: Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Data curation. **Bomi Hong:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Data curation. **Sun Young Rha:** Writing – review & editing, Methodology, Conceptualization. **Sungkun Cho:** Writing – review & editing, Conceptualization. **Hye Sun Lee:** Writing – review & editing, Formal analysis. **Jiyeon Lee:** Writing – review & editing, Writing – original draft, Methodology, Funding acquisition, Formal analysis, Conceptualization.

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Declaration of competing interest

None.

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Data availability

The data supporting the findings of the current study will be available by the corresponding author upon reasonable request.

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