

NURSE-LED ENHANCED SUPPORTIVE CARE AS AN EARLY PRIMARY PALLIATIVE CARE APPROACH FOR ADVANCED CANCER PATIENTS: A RANDOMIZED CONTROLLED TRIAL

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Introduction

Primary palliative care was introduced as a way to deliver early palliative care which refers to palliative care provided to patients receiving cancer treatments by oncology health care providers who are not palliative care specialists. Nurses play an important role in providing palliative care. However, few studies have evaluated the effectiveness of nurse-led primary palliative care.

Purpose

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

Methods

Design: Randomized controlled trial

Setting: Yonsei Cancer Center in Seoul, Korea.

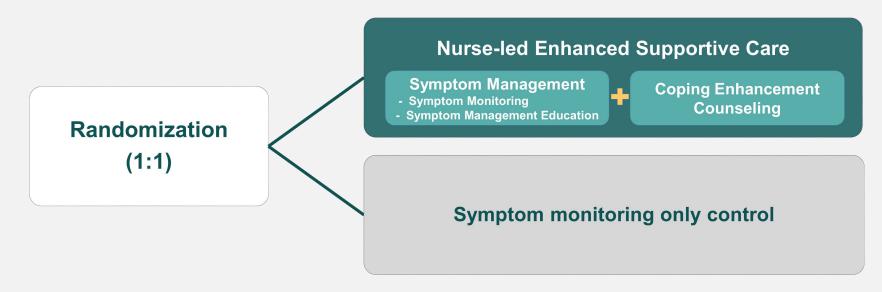
Participants: Advanced cancer patients initiating palliative chemotherapy (N=258) and their family caregivers (N=120) were enrolled and completed 3-month (n=182 patients, n= 79 caregivers) and 6-month (n=141 patients, n=60 caregivers) follow-up assessments.

Caregivers Patients Enrollment Enrollment Assessed for eligibility (n=512) Assessed for eligibility (n=161) Not meeting inclusion criteria (n= Declined to participate (n=41) Randomized (n=258) Randomized (n=120) Allocated to control group (n=115) Allocated to intervention group (n=68) Allocated to control group (n=52) Allocated to intervention group (n=143) ollow-Up (3 month Lost to follow-up (n=63) Lost to follow-up (n=13) Lost to follow-up (n=7 Withdrawal of consent (n=44) Lost to follow-up (n=34) Withdrawal of consent (n=6) Deterioration in physical condition (n=12 Deterioration in physical condition (n=2 Dropout due to patient withdrawal (n=6 Transfer to another hospital (n=3) Dropout due to patient withdrawal (n=33 ransfer to another hospital (n=2) Withdrawal of consent (n=1) Death (n=2) Withdrawal of consent (n=1) Death (n=1) Non-response to calls (n=1) Discontinuation of chemotherapy (n= Non-response to calls (n=2) Follow-Up (6 months) Lost to follow-up (n=18) Lost to follow-up (n=10) Lost to follow-up (n=6) Withdrawal of consent (n=7) Deterioration in physical condition (n=2) Transfer to another hospital (n=3) Withdrawal of consent (n=8 Dropout due to patient dropout (n=6) Propout due to patient dropout (n=5) Non-response to calls (n=1) Withdrawal of consent (n=1) Withdrawal of consent (n=1) Transfer to another hospital (n=1) Discontinuation of chemotherapy (n=2) At 3 months (n=80 At 3 months (n=102) At 3 months (n=34) At 3 months (n=45) At 6 months (n=24) Excluded from the 6-month analysis At 6 months (n=62) At 6 months (n=79) At 6 months (n=36) Excluded from the 6-month analyst Excluded from the 6-month analys xcluded from the 6-month analysis pecause data was not collected due to ecause data was not collected due the because data was not collected due to pecause data was not collected due th the research period's end (n=8) research period's end (n=5) ne research period's end (n=4) esearch period's end (n=1)

Figure 1. CONSORT flow diagram

Procedure

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.



Measurement

Figure 2. Study Design

<u>Primary outcomes</u>

Quality of life (EORTC-QLQ C30), Symptoms (ESAS), Coping (Brief COPE) at 3 months <u>Secondary outcomes</u>

QoL, Symptoms, and Coping at 6 months, Self-efficacy for coping with cancer (CBI-3.0 K), Depression among cancer patients and family caregivers (HADS-D) at 3 and 6 months *Analysis:* Linear mixed models (α =.05)

Results

The intervention group reported beneficial effects in the following outcomes.

1) Qo

Role functioning at 3 months

 $(1.01\pm2.34 \text{ vs.} -8.37\pm2.07; p=.003 [-15.57, -3.18]; adjusted p=.044)$

2) Coping

Active coping at 3 months

 $(0.27\pm0.16 \text{ vs.} -0.34\pm0.14; p=.006 [-1.04, -0.18]; adjusted p=.044)$

Self-distraction at 3 months

 $(0.22\pm0.17 \text{ vs. } -0.42\pm0.15; p=.004 [-1.08, -0.20]; adjusted p=.044)$

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).

Discussion

Nurse-led enhanced supportive care was not effective in improving overall quality of life and symptoms, but it was effective in changing some coping domains and self-efficacy for maintaining activity and independence at 3 months among advanced cancer patients.

Role functioning domain of QoL is one of the most commonly affected area among outpatients newly diagnosed with advanced cancer, and the role functioning domain of QoL demonstrated significant difference favoring the nurse-led enhanced supportive care at 3 months.

Non-significant symptom finding highlights the need for a comprehensive and intensive approach to symptom management for patients with advanced cancer.

Positive finding on active coping and self-distraction could be derived as outcome of coping enhancement counseling incorporating the component of ACT.

Increase in self-efficacy in maintaining activity and independence could be related to better symptom control or self-efficacy for managing side effect, however it did not differ between groups.

Conclusions

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

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