第一題: 請依據下列摘要，以中文回答 1.1 及 1.2 題組: 【作答時間有限，請注意各題時間分配】

(文章參考來源: Schenker Y, Althouse AD, Rosenzweig M, et al. Effect of an Oncology Nurse-Led Primary Palliative Care Intervention on Patients With Advanced Cancer: The CONNECT Cluster Randomized Clinical Trial. JAMA Intern Med. 2021;181(11):1451-1460.)

**Abstract**

**Importance:** Guidelines recommend early specialty palliative care for all patients with advanced cancer, but most patients lack access to such services.

**Objective:** To assess the effect of CONNECT (Care Management by Oncology Nurses to Address Supportive Care Needs), a primary palliative care intervention delivered by oncology nurses, on patient outcomes.

**Design, setting, and participants:** This cluster randomized clinical trial of the CONNECT intervention vs standard care was conducted. Participants were adult patients with metastatic solid tumors who were undergoing oncological care and for whom an oncologist would agree with the statement "would not be surprised if the patient died in the next year." The trial was conducted at 17 community oncology practices in western Pennsylvania. Data analyses adhered to the intention-to-treat principle.

**Interventions:** The CONNECT intervention included 3 monthly visits with an existing infusion room nurse who was trained to address symptoms, provide emotional support, engage in advance care planning, and coordinate care.

**Main outcomes and measures:** The primary outcome was quality of life. At baseline and 3 months, participants completed assessments of quality of life (Functional Assessment of Chronic Illness Therapy-Palliative care: score range, 0-184, with higher scores indicating better quality of life), symptom burden (Edmonton Symptom Assessment Scale: score range, 0-90, with higher scores indicating greater symptom burden), and mood symptoms (Hospital Anxiety and Depression Scale [HADS]: score range, 0-21, with higher scores indicating substantial anxiety and depression). Linear mixed-effects models were used to estimate adjusted mean differences in 3-month outcomes. Preplanned, intensity-adjusted analyses were conducted.

**Results:** A total of 672 patients were enrolled (mean [SD] age, 69.3 [10.2] years; 360 women [53.6%]). The mean (SD) number of CONNECT visits completed was 2.2 (1.0). At 3 months, no difference in mean (SD) quality-of-life score was found between the CONNECT and standard care groups (130.7 [28.2] vs 134.1 [28.1]; adjusted mean difference, 1.20; 95% CI, -2.75 to 5.15; P = .55). Similarly, there was no difference between groups in 3-month mean (SD) symptom burden (23.2 [16.6] vs 24.0 [16.1]; adjusted mean difference, -2.64; 95% CI, -5.85 to 0.58; P = .11) or mood symptoms (HADS depression subscale score: 5.1 [3.4] vs 4.8 [3.7], adjusted mean difference, -0.08 [95% CI, -0.71 to 0.57], P = .82; HADS anxiety subscale score: 5.7 [3.9] vs 5.4 [4.2], adjusted mean difference, -0.31 [95% CI, -0.96 to 0.33], P = .34). Intensity-adjusted analyses revealed a larger estimated treatment effect for patients who received a full dose (3 visits) of the CONNECT intervention.

**Conclusions and relevance:** This cluster randomized clinical trial found that a primary palliative care intervention that was delivered by oncology nurses did not improve patient-reported outcomes at 3 months. Primary palliative care interventions with a higher dose intensity may be beneficial for most patients with advanced cancer who lack access to palliative care specialists.

1.1 請說明本研究之(1)研究目的，(2)研究設計，(3)研究收案點，(4)研究受試者，(5)主要介入措施。(20%)

1.2 請說明本研究之(1)主要研究結果與(2)重要結論。(20%)

見背面

**第二題: 請依據下列摘要，以中文回答系列題組:**

(文章摘要參考來源: Bosque D, Delaney J, Forbes SG, Brassil KJ. Implementation and Evaluation of a Clinical Trial Communication Tool for Frontline Clinical Staff. Clin J Oncol Nurs. 2023;27(6):663-667. doi:10.1188/23.CJON.663-667.)

Clinical trials are increasingly complex in design and procedure, requiring interprofessional involvement and communication to maximize participant safety (Malik & Lu, 2019). Communication between interprofessional teams is essential when coordinating and delivering care across the cancer care continuum (Chollette et al., 2022). The purpose of this quality improvement initiative was to design, implement, and evaluate the efficacy of a new, standardized approach for communicating and accessing trial information to clinical staff across the health system.

**TABLE 1.**
RESEARCH PROTOCOL FACT SHEET ESSENTIAL INFORMATION

| SECTION OF TEMPLATE | RELEVANT INFORMATION INCLUDED BY THE STUDY TEAM |
|---|---|
| Protocol | ■ Institutional protocol number<br>■ Clinical trial title |
| Contact information | ■ Principal investigator: name, email address, contact number(s)<br>■ Clinical research nurse or study coordinator: name, email address, contact number(s) |
| Objectives | ■ Protocol primary objective(s) |
| Mechanism of action | ■ Study drug description and mechanism of action<br>■ Any other drugs' mechanisms of action: U.S. Food and Drug Administration–approved drugs hyperlinked to the online institutional drug reference database |
| Administration and monitoring | ■ Overview of medications and treatment administered to patient: essential nursing considerations including route, timing, premedications, and monitoring parameters<br>■ Does not include doses or infusion times that may be confused with treatment plan or outdated with protocol amendments<br>■ States that "this is not an order. Refer to the treatment plan for order." |
| Protocol research collections | ■ Non–standard-of-care specimen collections (e.g., pharmacokinetics, pharmacodynamics, biomarkers, bone marrow aspirations, tumor biopsies)<br>■ Electrocardiograms and timing specific to protocol<br>■ Information on departmental collections, contact information, and transportation of samples |
| Reactions and toxicities | ■ Study drugs' known reaction and toxicities<br>■ Any other drugs' reaction and toxicities: U.S. Food and Drug Administration–approved drugs hyperlinked to the online institutional drug reference database |
| Additional protocol comments and considerations | ■ Other relevant information the study team wants to communicate to the clinical frontline nurses<br>■ May include dietary instructions or restrictions<br>■ May include prohibited or contraindicated medications or treatment |

**Note.** The Research Protocol Fact Sheet is copyrighted by the University of Texas MD Anderson Cancer Center. Adapted with permission.

2.1 請以中文說明本研究之(1)研究背景與重要性，(2)研究目的。(8%)

2.2 請以中文說明本研究發展出來的 Fact Sheet 主要包含哪八大項目，最後一項「additional protocol comments and considerations」所應包含之資訊有哪些? (22%)

接次頁

第三題: 簡要闡述「臨床研究護理師」之專業角色與職責。(10%)

第四題: 說明執行「知情同意」需考慮之核心要件有哪些? (10%)

第五題: 簡要說明第一期與第二期臨床試驗的目的、重點特色及常見之納入人數。(10%)

試題隨卷繳回