# Study Protocol and Statistical Analysis Plan (SAP)

**Cover Page**

Official title: Effectiveness of a nurse-led, culturally adapted palliative and end-of-life training program (N-PELTP) for oncology nurses: A quasi-experimental controlled study

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# 1. Study Protocol

## 1.1 Background and rationale

Palliative and end-of-life care is a core component of comprehensive oncology care. Oncology nurses frequently encounter patients and families with complex symptom burdens and psychosocial needs and are expected to communicate effectively about goals of care, symptom management, and end-of-life issues. However, nurses' preparation for palliative and end-of-life care may be variable, and access to structured, contextually relevant education may be limited. Culturally responsive training programs can strengthen workforce readiness and improve communication and care practices in oncology settings.

This study evaluates a nurse-led, culturally adapted palliative and end-of-life care training program (N-PELTP) delivered to oncology nurses in Oman.

## 1.2 Aim

To evaluate the effectiveness of a nurse-led, culturally adapted palliative and end-of-life training program (N-PELTP) for oncology nurses.

## 1.3 Objectives

1. To assess changes in oncology nurses' attitudes toward caring for dying patients following participation in N-PELTP.

2. To assess changes in self-reported palliative care practices following participation in N-PELTP.

3. To assess changes in communication-related outcomes following participation in N-PELTP.

4. To assess changes in oncology nurses' palliative and end-of-life care knowledge following participation in N-PELTP.

5. To compare changes in outcomes between the intervention and control groups.

## 1.4 Study design

Quasi-experimental controlled pretest–posttest study with two parallel groups: (1) Intervention group receiving N-PELTP; and (2) Control group continuing usual practice during the study period (no training during the intervention phase).

## 1.5 Study setting

Oncology/cancer care settings in Muscat, Oman, including the Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC), University Medical City, and the Royal Hospital.

## 1.6 Study population

Registered nurses working in participating oncology settings and providing direct patient care.

## 1.7 Eligibility criteria

### Inclusion criteria

- Registered nurses working in participating oncology/cancer care settings in Oman.
- Providing direct clinical care to patients with cancer.
- Aged 18 years or older.
- Able to read and understand study materials and questionnaires.
- Provide informed consent.
- Available to complete baseline assessment and follow-up assessments during the study period.

### Exclusion criteria

- Nursing students, interns, or non-registered nursing staff.
- Nurses not providing direct patient care (administrative-only roles).
- Nurses on extended leave during the intervention and follow-up period.
- Nurses who did not complete the baseline assessment.

## 1.8 Intervention

N-PELTP (Nurse-led Palliative and End-of-life Learning and Training Program) is a structured, nurse-led, culturally adapted education and training program in palliative and end-of-life care for oncology nurses. The program targets core palliative competencies, including communication and care planning, and is delivered in a structured format over a defined training period. The program is delivered by qualified facilitators and includes learning activities appropriate to the local context.

## 1.9 Comparator

Control participants continue usual practice during the study period and do not receive N-PELTP during the intervention phase. Assessments are conducted at the same time points as the intervention group.

## 1.10 Outcomes

### Primary outcomes

- Attitudes toward caring for dying patients score (baseline and 2 weeks post-intervention).
- Self-reported palliative care practice score (baseline and 2 weeks post-intervention).
- Communication-related outcomes score (baseline and 2 weeks post-intervention).
- Palliative and end-of-life care knowledge score (baseline and immediately post-intervention).

## 1.11 Data collection schedule

Baseline (pre-intervention): all outcomes.

Immediately post-intervention: knowledge outcome.

Two weeks post-intervention: attitudes, practice, and communication outcomes.

## 1.12 Sample size

The study enrolled 189 participants in total (89 intervention, 100 control).

## 1.13 Recruitment and consent

Eligible nurses are informed about the study and invited to participate. Written informed consent is obtained prior to enrollment. Participation is voluntary and participants may withdraw at any time without penalty.

## 1.14 Ethical considerations

The study is conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent is obtained from all participants. Data are anonymized using study codes, stored securely, and accessed only by the research team. Findings are reported in aggregate to protect confidentiality.

## 1.15 Ethics approvals

- Research and Ethics Committee, College of Nursing, Sultan Qaboos University (CON/MSN/2025/8; approved 17 March 2025).
- Institutional Review Board and Ethics Committee of the Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCR-IRB&EC-2025-28-1; approved 16 April 2025).
- Scientific Research Committee, Ministry of Health, Oman (MoH/CSR/25/29653; approved 25 March 2025).

## 1.16 Data management and confidentiality

Data are collected using standardized questionnaires, stored in password-protected files, and de-identified prior to analysis. Only authorized members of the research team have access to the dataset.

## 1.17 Dissemination

Findings will be disseminated through peer-reviewed publication and academic presentations.

## 2. Statistical Analysis Plan (SAP)

### 2.1 General approach

Analyses will be conducted using appropriate statistical software. All tests will be two-sided, and statistical significance will be set at $p < 0.05$ unless otherwise specified. Descriptive statistics will summarize participant demographics and baseline characteristics.

### 2.2 Analysis populations

Enrolled population: all participants who consented and completed baseline assessment.

Complete-case analysis: participants with baseline and relevant follow-up outcome data for each outcome.

The number of missing observations and reasons for missingness will be summarized.

### 2.3 Baseline comparability

Baseline characteristics will be compared between intervention and control groups using chi-square or Fisher's exact tests for categorical variables and independent samples t-test or Mann–Whitney U test for continuous variables (based on distribution).

### 2.4 Primary outcomes analysis (attitude, practice, communication)

For each primary outcome (attitudes, self-reported practice, and communication), change from baseline to 2 weeks post-intervention will be assessed:

- Within-group change: paired t-test (or Wilcoxon signed-rank test if non-normal).
- Between-group comparison of follow-up scores and/or change scores: independent t-test (or Mann–Whitney U test as appropriate).
- If assumptions of equal variances are not met, Welch's t-test will be applied.
- If baseline differences are present, an adjusted analysis may be conducted using ANCOVA with the follow-up score as the dependent variable, group as the independent variable, and baseline score as covariate.

Change in knowledge scores from baseline to immediately post-intervention will be assessed using paired t-test (or Wilcoxon signed-rank test) for within-group change and independent t-test (or Mann–Whitney U test) for between-group comparisons. Welch's correction will be used when variance assumptions are not met.

### 2.6 Handling missing data

Missing data will not be imputed in the primary analysis unless pre-specified. The amount of missing data will be reported. Sensitivity analyses may be conducted if missingness is substantial.

## 2.7 Subgroup / exploratory analyses

If pre-specified and feasible, exploratory subgroup analyses may be conducted by nurse characteristics (e.g., years of experience or prior exposure to palliative training). These analyses will be interpreted cautiously.

## 2.8 Reporting

Results will be presented with effect estimates (mean differences or median differences as appropriate) and corresponding confidence intervals where applicable, alongside p-values.