CONCISE STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Advance Care Planning Impact on the Consistency of Older Adults With Lung Cancer and Their Potential Surrogates Regarding Life-Sustaining Treatment Preferences

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Translation statement

This document is a concise English translation and consolidation of the protocol approved by Research Ethics Committee D of National Taiwan University Hospital and its prespecified statistical methods. It contains no study results. The original approved-language documents remain the governing protocol.

1. Protocol Synopsis

Item	Protocol specification
Design	Single-center, randomized, parallel-group, open-label behavioral trial; 1:1 allocation.
Study unit	One patient with lung cancer and one designated potential surrogate (a dyad).
Planned enrollment	62 dyads (124 individual participants), including allowance for attrition.
Arms	Scenario-based ACP tabletop game versus standardized ACP manual.
Follow-up	Baseline (T0), immediately post-intervention (T1; STAI-S only), 2 weeks (T2), and 6 weeks (T3).
Primary outcome	Dyad-level absolute gap in total modified Life Support Preferences Questionnaire (m-LSPQ) score at T0, T2, and T3.
Secondary outcomes	Five treatment-specific m-LSPQ absolute gaps and patient/surrogate State-Trait Anxiety Inventory-State (STAI-S) scores.
Primary analysis	Generalized estimating equations (GEE), normal distribution, identity link, AR(1) working correlation, robust sandwich variance, and Wald chi-square tests.

2. Background, Objectives, and Hypotheses

Advance care planning (ACP) supports discussion of values and future medical care. Patient-surrogate preferences may differ, and serious illness discussions can be difficult to initiate. A scenario-based tabletop game may provide a structured, less threatening way for older adults with lung cancer and their potential surrogates to discuss life-sustaining treatment preferences.

Primary objective: to evaluate whether the ACP tabletop game changes the dyad-level absolute gap in total m-LSPQ score over 6 weeks compared with a standardized ACP manual.

Secondary objectives: to evaluate treatment-specific preference gaps and state anxiety in patients and surrogates. The primary hypothesis is that change in the total m-LSPQ absolute gap will differ between groups; smaller gaps indicate greater concordance.

3. Study Design and Setting

This is a randomized, parallel-group behavioral intervention trial conducted at National Taiwan University Hospital, Taipei, Taiwan. Recruitment occurs in thoracic medicine, thoracic surgery, oncology clinics, and inpatient units. Participants and the intervention facilitator cannot be masked because the interventions are visibly different. Allocation remains concealed until written consent and baseline assessment are completed.

4. Participants

Category	Criteria

Category	Criteria
Patient inclusion	Lung cancer; age 60 years or older; conscious; able to communicate in Mandarin or Taiwanese; able to designate a potential surrogate; written informed consent.
Surrogate inclusion	Designated by the patient as a potential future decision-support person; age 18 years or older; able to communicate in Mandarin or Taiwanese; written informed consent.
Exclusion	Cognitive impairment preventing meaningful participation or consent; severe hearing or visual impairment preventing study procedures; inability to communicate in Mandarin or Taiwanese; refusal or withdrawal by either dyad member.

5. Sample Size, Recruitment, and Randomization

A repeated-measures sample-size calculation (two-sided alpha 0.05, power 0.80, three m-LSPQ assessment times, low-to-moderate effect size 0.23) indicated 52 dyads. Allowing approximately 20% attrition, 62 dyads (124 individuals) were planned.

Treating physicians identify potentially eligible patients. A trained researcher explains the study and obtains written consent separately from both dyad members. A computer-generated random sequence is placed in sequentially numbered, sealed, opaque envelopes prepared by an independent researcher. Envelopes are opened after baseline procedures to allocate each dyad 1:1.

6. Interventions

Arm	Intervention
ACP tabletop game	The scenario-based game “Walking with Wishes” uses a board, cards, dice, and prompts to discuss five life-sustaining treatments across hypothetical health scenarios. A trained facilitator guides the dyad in a quiet setting. Expected duration: approximately 40-120 minutes.
ACP manual	A standardized printed ACP manual addresses values, medical decision-making, palliative care, advance directives, and relevant patient-rights information. A researcher provides a brief introduction, followed by independent review. Expected duration: approximately 10-15 minutes.

7. Assessment Schedule

Assessment	T0 Baseline	T1 Immediate	T2 2 weeks	T3 6 weeks
Eligibility, consent, baseline characteristics	Yes	No	No	No
m-LSPQ (patient and surrogate)	Yes	No	Yes	Yes
STAI-S (patient and surrogate)	Yes	Yes	Yes	Yes
Intervention delivery	After T0	No	No	No

8. Outcome Measures

8.1 Modified Life Support Preferences Questionnaire (m-LSPQ)

The m-LSPQ contains 45 items: five treatments (antibiotics, CPR, surgery, nasogastric tube feeding, and intravenous infusion) across nine health scenarios. Items are rated from 1 (absolutely unwanted) to 5 (absolutely wanted). Total scores range from 45 to 225; each treatment subscale ranges from 9 to 45. Higher scores indicate a greater preference for receiving the treatment.

Patient and surrogate scores are calculated separately. The dyad-level absolute gap is |surrogate score - patient score|. The total gap ranges from 0 to 180 and each subscale gap from 0 to 36; smaller values indicate greater concordance.

8.2 State-Trait Anxiety Inventory-State (STAI-S)

The STAI-S contains 20 items and measures current state anxiety. Scores range from 20 to 80; higher scores indicate greater anxiety. Patient and surrogate scores are analyzed separately.

8.3 Baseline Variables

Baseline variables include age, sex, education, cancer stage for patients, relationship of surrogate to patient, and Charlson Comorbidity Index. Variables are reported separately for patients and surrogates as applicable.

9. Data Management, Safety, and Ethics

Participants receive unique study codes. Identifiers are stored separately from study data, and access is limited to authorized personnel. Questionnaires are checked for completeness and discrepancies are resolved against source records.

The study is a minimal-risk communication intervention. Participants may skip questions, pause, or withdraw. The facilitator stops or modifies the session if meaningful distress occurs and advises contact with the clinical team when appropriate.

Research Ethics Committee D of National Taiwan University Hospital approved the protocol (202407186RIND) on September 13, 2024. Written informed consent is obtained from both dyad members before study procedures.

10. Statistical Analysis Plan

10.1 General Principles and Analysis Populations

Analyses use IBM SPSS Statistics version 22.0. All tests are two-sided with alpha 0.05; 95% confidence intervals are reported. No interim analysis is planned.

- Participant flow: all randomized individual participants, summarized by arm and reason for non-completion.
- m-LSPQ gap analyses: dyads with both patient and surrogate scores available at the relevant time point; inferential unit is the dyad.
- STAI-S analyses: patients and surrogates with available data, analyzed separately by role.
- No outcome imputation is planned; available observations contribute to analyses. A gap is not calculated when either dyad member lacks the corresponding score.

10.2 Descriptive and Baseline Analyses

Continuous variables are summarized using number analyzed, mean, and standard deviation. Categorical variables are summarized using frequencies and percentages. Baseline group comparisons use independent-samples t tests for continuous variables and chi-square or appropriate exact tests for categorical variables.

10.3 Longitudinal GEE Analyses

The primary GEE model analyzes the total m-LSPQ absolute gap at T0, T2, and T3. Separate GEE models analyze each treatment-specific gap. Patient and surrogate STAI-S scores are analyzed in separate models at T0, T1, T2, and T3.

Each model uses a normal distribution, identity link, AR(1) working correlation, and robust sandwich variance estimator. Fixed effects are group, categorical time, and group-by-time interaction. The control group at T0 is the reference.

Coefficient	Interpretation
Group	Baseline difference between the experimental and control groups.
Time	Change from baseline in the control group at the specified follow-up.
Group x Time	Between-group difference in change from baseline; principal intervention-effect contrast.

For each coefficient, the estimate, robust standard error, Wald chi-square test, two-sided p value, and 95% confidence interval are reported. No covariates are included in the primary model. No formal multiplicity adjustment is planned; secondary analyses are interpreted as supportive.

11. Protocol Deviations and Reporting

Reasons for missing data, withdrawal, and non-completion are summarized by arm. Major deviations affecting eligibility, intervention receipt, or outcome availability are documented. Public reporting presents patient and surrogate scores separately and the derived dyad-level gaps in structured results tables.