Supplementary Appendix I: CONSORT 2025 checklist

Section/topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	Page 1
	1b	Structured summary of the trial design, methods, results, and conclusions	Page 3-4
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	Page 6
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	Page 6 and Supplementary Appendix IV
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	Not explicitly reported
Funding and conflicts of interest	5a	Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	Page 23
	5b	Financial and other conflicts of interest of the manuscript authors	Page 23
Introduction			
Background and rationale	6	Scientific background and rationale	Page 5-6
Objectives	7	Specific objectives related to benefits and harms	Page 6
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	Page 6-7
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	Page 6-7
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	Not applicable
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted	Page 6
Eligibility criteria	12a	Eligibility criteria for participants	Page 6-7
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)	Not applicable
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	Page 7-9, Figure 1
Outcomes	14	Prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	Page 9-11
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	Page 9
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	Page 12

	16b	Explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	Page 7
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)	Page 7
			Reported on page no.
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	Page 7
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	Page 7
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)	Page 7
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	Page 7
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	Page 12-13
	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group	Page 12
	21c	How missing data were handled in the analysis	Page 12
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing prespecified from post hoc	Page 13-14
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	Page 14, Figure 2
	22b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	Page 14
	23b	If relevant, why the trial ended or was stopped	Not applicable
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended (fidelity))	Page 15, Appendix V: Supplementary Figure 1
	24b	Concomitant care received during the trial for each group	Page 15, Appendix V: Supplementary Figure 1
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis ● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size	Page 14-15, Table 2, Figure 3
Harms	27	All harms or unintended events in each group	Not applicable (No harm)
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	Page 16-17, Appendix V: Supplementary

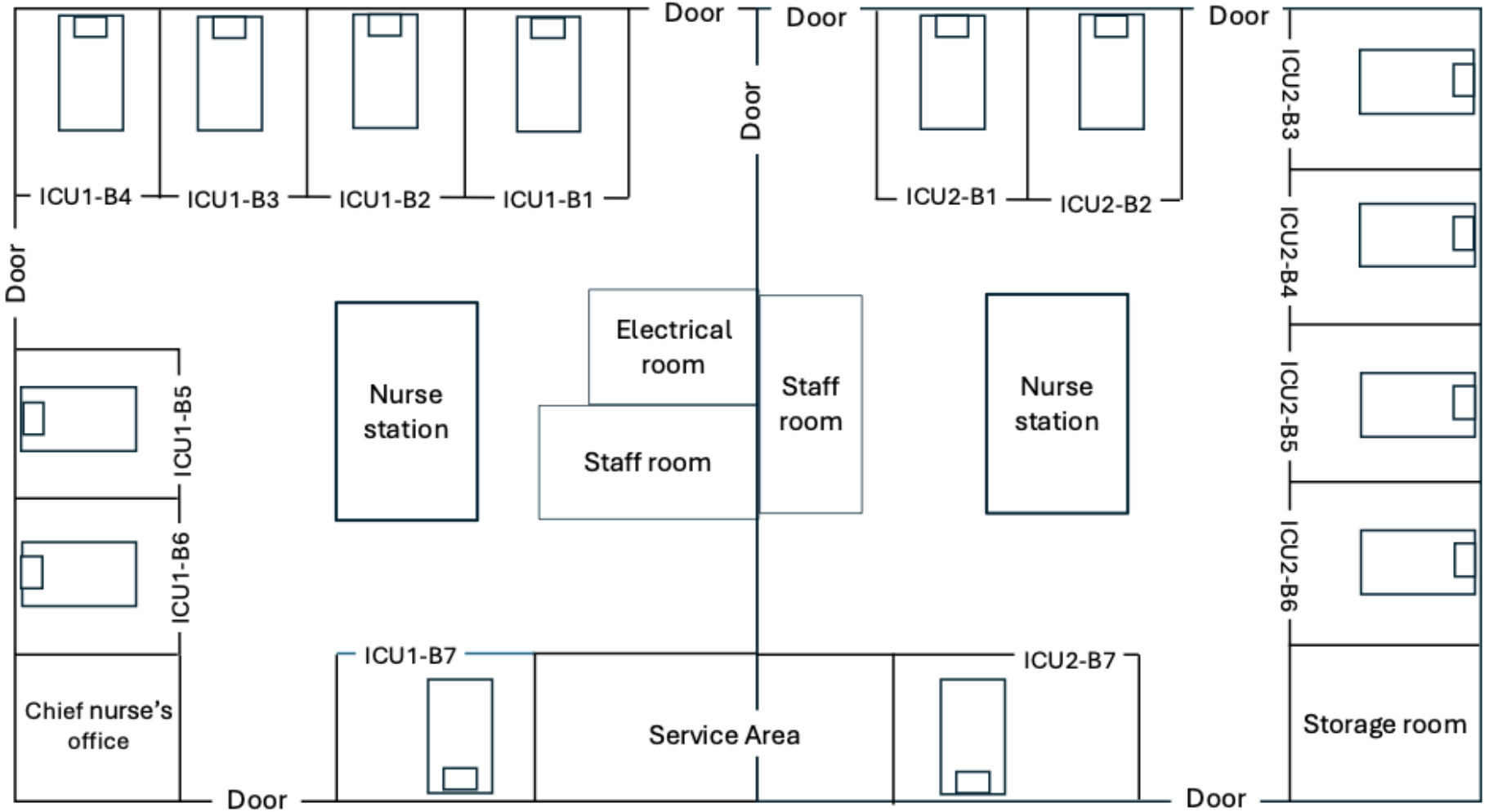
			Table 2-4 and Supplementary Figure 3-6
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 18-20
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	Page 20-21

Citation: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: Updated Guideline for Reporting Randomized Trials. Jama. 2025;333(22):1998-2005.

*We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.

Supplementary Appendix II

A schematic diagram of the ICU layout



Supplementary III.

Original Richard Campbell Sleep Questionnaire (RCSQ)

Richards Campbell Sleep Questionnaire (RCSQ)

Code Number_____ Date_____

Each of these questions is answered by placing an "X" on the answer line. Place your "X" ***anywhere*** on the line that you feel ***best*** describes your sleep last night. The following are examples of the type of questions you are to answer.

EXAMPLE A

Right now I feel:

Very Sleepy X _____ ***Not sleepy at all***

If you were very sleepy, you would place an "X" as is shown at the beginning of the line next to the words "***Very Sleepy***."

EXAMPLE B

Right now I feel:

Very Sleepy _____ X _____ ***Not sleepy at all***

If you were somewhat sleepy, you would place an "X" near the center of the line. Mark the answer line near the center to indicate the answer "***Somewhat Sleepy***."

EXAMPLE C

Right now I feel:

Very Sleepy _____ X ***Not sleepy at all***

If you were not sleepy at all, you would place an "X" at the end of the line next to the words "***Not Sleepy At All.***"

Please turn to next page

You are now ready to begin to answer the questions. Place your "X" ***anywhere*** on the answer line that you feel ***best*** describes your sleep last night.

1. My sleep last night was:

Deep Sleep _____ ***Light Sleep***

2. Last night, the first time I got to sleep, I:

Fell Asleep Almost Immediately _____ ***Just Never Could Fall Asleep***

3. Last night I was:

Awake Very Little _____ ***Awake All Night Long***

4. Last night, when I woke up or was awakened, I:

Got Back To Sleep Immediately _____ ***Couldn't Get Back To Sleep***

5. I would describe my sleep last night as:

A Good Night's Sleep _____ ***A Bad Night's Sleep***

Optional Noise Item:

6. I would describe the noise level last night as:

Very Quiet _____ ***Very Noisy***

Supplementary Appendix IV

Statistical analysis plan (SAP)

Version 1.0 – March 01, 2025

Study Title: Effects of a Multicomponent Sleep Enhancement Protocol on Delirium Incidence in Elderly Critically Ill Surgical Patients: A Randomized Controlled Trial

Trial Registration: TCTR20221129003

Investigators: Nuanprae Kitisin, Suchanun Lao-amornphunkul, Nattachai Hemtanon, Napat Thikom, Nawarat Phochan, Chayanan Thanakiattiwibun, Onuma Chaiwat, Karuna Wongtangman, Paranee Trachuthamcharoen, Annop Piriyapatsom, Laurence Weinberg, Ary Serpa Neto, Nattaya Raykateeraroj

Introduction

Sleep disturbances are common in intensive care unit (ICU) patients and are associated with poor outcomes, including delirium. This randomized controlled trial (RCT) evaluates whether a non-pharmacologic multicomponent sleep enhancement protocol reduces the incidence of delirium in elderly critically ill surgical patients. This Statistical analysis plan (SAP) outlines the pre-specified statistical methodology.

Study design

This is a single-center, prospective, single-blinded, parallel-group RCT conducted in a surgical ICU. Patients aged ≥65 years were randomized 1:1 to receive either a multicomponent sleep protocol or standard ICU care. Randomization was stratified by time of admission and conducted in blocks of two. Outcome assessors were blinded to group allocation.

Study population

Eligible patients were ≥65 years old, admitted to the ICU within 7 days post-surgery, anticipated to stay >24 hours, and hemodynamically stable. Patients with pre-existing cognitive dysfunction, sensory impairments, deep sedation, or delirium at ICU admission were excluded.

Intervention

The intervention group received environmental (light, noise, alarm) and patient-specific (earplugs, eye masks) modifications nightly for up to 7 ICU nights. The control group received usual ICU care.

Outcomes

Primary Outcome: Incidence of delirium within 7 ICU days, assessed twice daily using the Thai version of the Confusion Assessment Method for the ICU (CAM-ICU).

Secondary Outcomes: Delirium characteristics (onset, duration, and subtype), Richards-Campbell Sleep Questionnaire (RCSQ) sleep quality scores, antipsychotic use, self-extubation or catheter removal, ICU and hospital length of stay (LOS), ICU and hospital mortality, and nighttime noise levels.

Subgroup analysis: Patients at high risk for delirium, defined by a predictive score ≥125. This score incorporates factors such as age, Sequential Organ Failure Assessment (SOFA) score, perioperative benzodiazepine use, diabetes mellitus, mechanical ventilation, and cognitive decline (defined as modified Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) > 3.42).

Sample size

Sample size was based on frequentist estimates, assuming a 19% absolute reduction in delirium incidence (33% to 14%) with $\alpha = 0.05$ and power = 90%, yielding 77 patients per group. To allow for potential dropout, the target was increased to 92 per group (n = 184)

Statistical analysis

All analyses will follow a modified intention-to-treat approach, excluding patients who withdraw before receiving the intervention. If more than 5% of the primary outcome data are missing, multiple imputation using chained equations will be performed under the assumption of missing at random. Analyses will be conducted using R (v4.3.2) (R Core Team, 2016, Vienna, Austria).

Baseline characteristics will be summarized by treatment group. Categorical variables will be presented as frequencies and percentages. Continuous variables will be summarized using means with standard deviations or medians with interquartile ranges, depending on data distribution. No imputation will be performed for baseline data; the denominator will reflect available cases.

A Bayesian framework will be applied for all analyses. Binary outcomes (e.g., delirium incidence, antipsychotic use) will be analyzed using Bayesian logistic regression. Continuous outcomes (e.g., RCSQ scores, length of stay) will be analyzed using Bayesian linear regression. For skewed distributions, asymmetric Laplace regression (i.e., Bayesian quantile regression) will be used. Results will be reported as posterior estimates—odds ratios (ORs), mean or median differences (MDs)—with 95% credible intervals (CrIs) and posterior probabilities of benefit (e.g., $P(OR < 1)$, $P(MD > 0)$). Given the exploratory nature, early-phase, and limited sample size of this study, a posterior probability of ≥90% in favor of treatment benefit will be interpreted as suggestive evidence. This threshold is consistent with conventions used in early-phase Bayesian trials and is pre-specified to support transparent interpretation of findings (1). Subgroup analyses in high-risk patients will be conducted using the same modelling framework.

Weakly informative priors will be applied to all models. For logistic regression, Normal(0, 2.5) priors will be used on the log-odds scale. Quantile regression coefficients will be assigned Normal(0, 5) priors. Intercepts and random effects will be modelled using Student-t distributions with 3 degrees of freedom (t[3, 0, 2.5]).

A sensitivity analysis for the primary outcome will be conducted if notable baseline imbalances are identified, adjusting for those variables using the same Bayesian logistic regression framework. If no substantial imbalances are present, no sensitivity analysis will be performed.

Reference

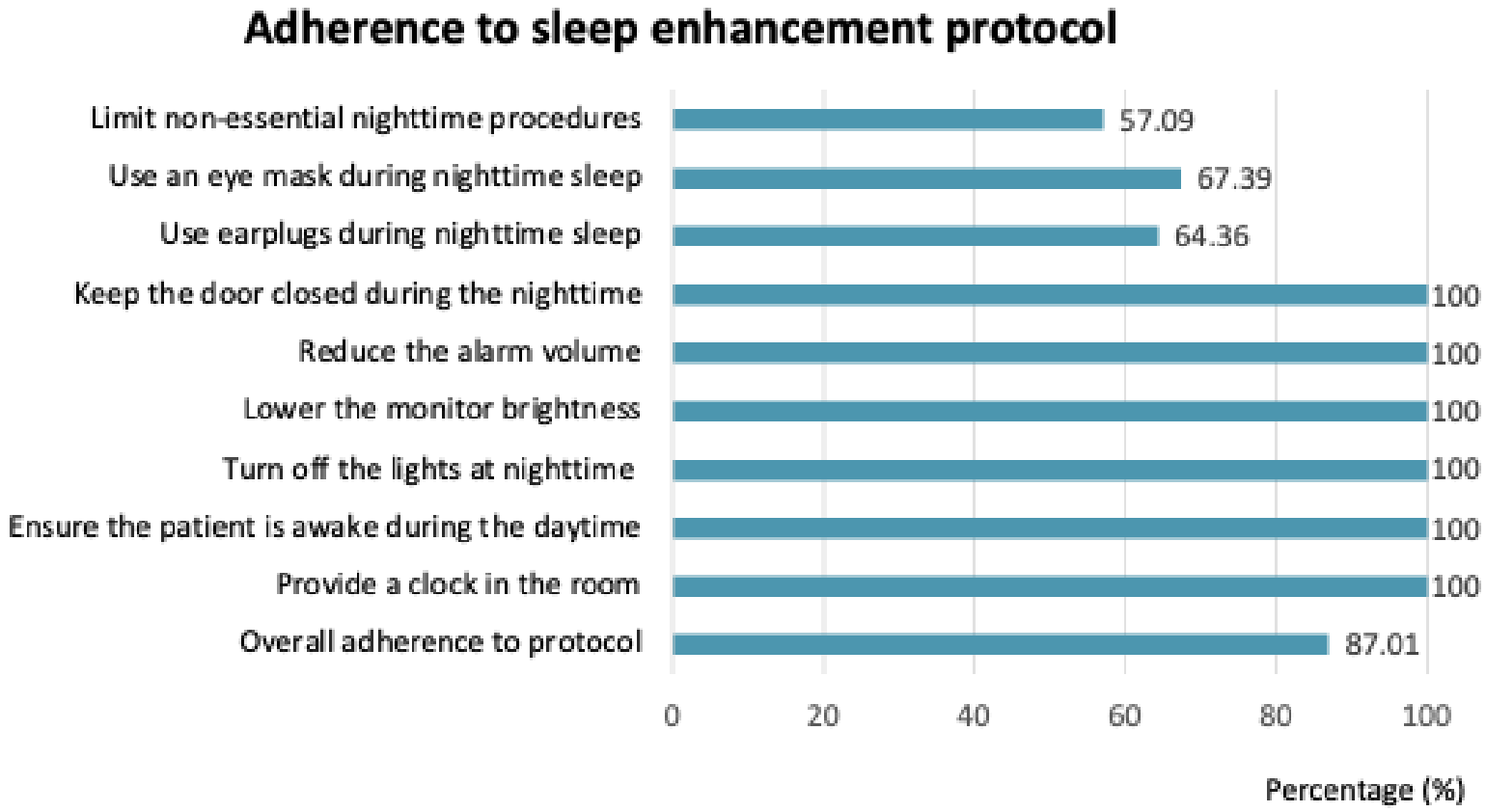
1. Food US, Administration D. Guidance for industry: Bioanalytical method validation. Rockville, MD: U.S. Department of Health and Human Services, Food and Drug Administration; 2006.

Appendix V: Supplementary Table 1. Intraoperative and postoperative clinical characteristics of critically ill surgical patients.

Variables	Intervention (n = 89)	Control (n = 88)
Operative time (minutes)	240.0 (130.0 – 360.0)	210.0 (115.0 – 351.3)
Fluid volume		
Crystalloid infused volume (Liters)	2.3 (1.0 – 4.0)	2.0 (0.7 – 3.8)
Blood transfusion (Liters)	0.6 (0.3 – 3.9)	0.6 (0.23 – 2.6)
Intraoperative blood loss (Liters)	1.4 (0.4 – 5.7)	1.20 (0.4 – 5.0)
Intraoperative medication		
Fentanyl usage	83 (83.3%)	82 (93.2%)
Fentanyl dosage (µg)	100.0 (57.5 – 100.0)	100.0 (75.0 – 100.0)
Morphine usage	24 (27.0%)	28 (31.8%)
Morphine dosage (mg)	4.5 (3.0 – 8.3)	4.5 (3.0 – 7.3)
Midazolam usage	24 (27.0%)	26 (29.6%)
Midazolam dosage (mg)	2.0 (1.0 – 3.0)	2.0 (1.0 – 2.5)
Postoperative laboratory data		
Hematocrit (%)	31.0 (27.3 – 34.7)	30.75 (26.88 – 35.10)
Sodium (mg/dL)	138.0 (135.0 – 140.0)	138 (136 – 140)
ICU medications		
Fentanyl usage	68 (76.4%)	67 (76.1%)
Fentanyl dosage (µg)	565.0 (196.0 – 1,282.0)	650.0 (220.0 – 990.0)
Morphine usage	46 (51.7%)	44 (50.0%)
Morphine dosage (mg)	4.4 (2.0 – 10.0)	3.7 (2.5 – 8.0)
Midazolam usage	9 (10.1%)	11 (12.5%)
Midazolam dosage (mg)	2.5 (2.0 – 3.8)	2.0 (2.0 – 5.0)
Dexmedetomidine usage	7 (7.9%)	7 (8.0%)
Dexmedetomidine dosage (µg)	92.0 (72.0 – 163.0)	160.0 (82.0 – 220.0)
Ketamine usage	1 (1.1%)	2 (2.3%)
Ketamine dosage (mg)	811.0 (811.0 – 811.0)	559.0 (332.0 – 786.0)
Nefopam usage	6 (6.7%)	6 (6.8%)
Nefopam dosage (mg)	62.0 (41.0 – 80.0)	83.8 (65.0 – 96.9)

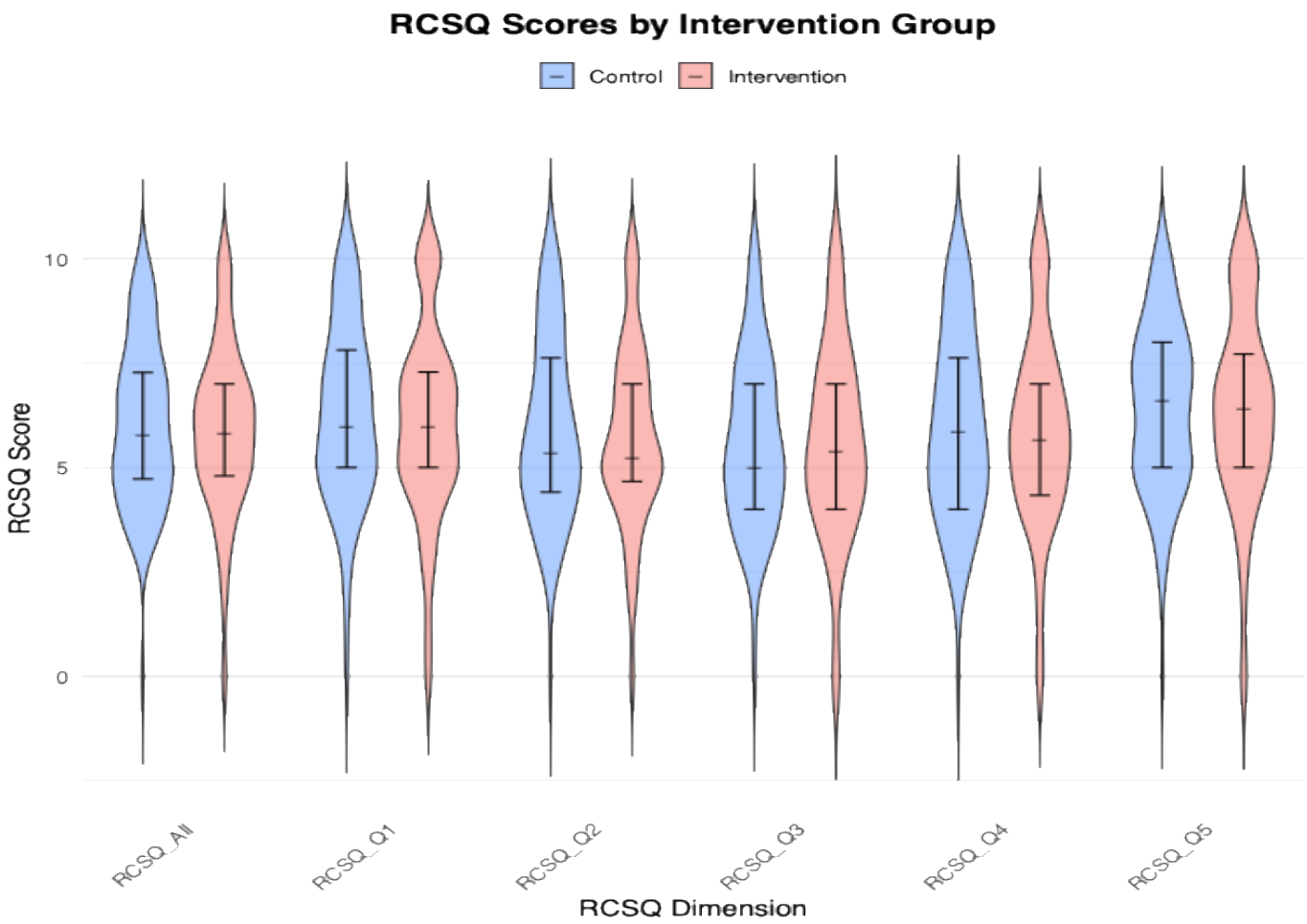
Data are presented as n (%) for categorical variables, mean ± standard deviation or median (interquartile range) for continuous variables. * p-value < 0.05 is considered statistically significant. ICU: Intensive care unit.

Appendix V: Supplementary Figure 1. Adherence to individual components of the sleep enhancement protocol.



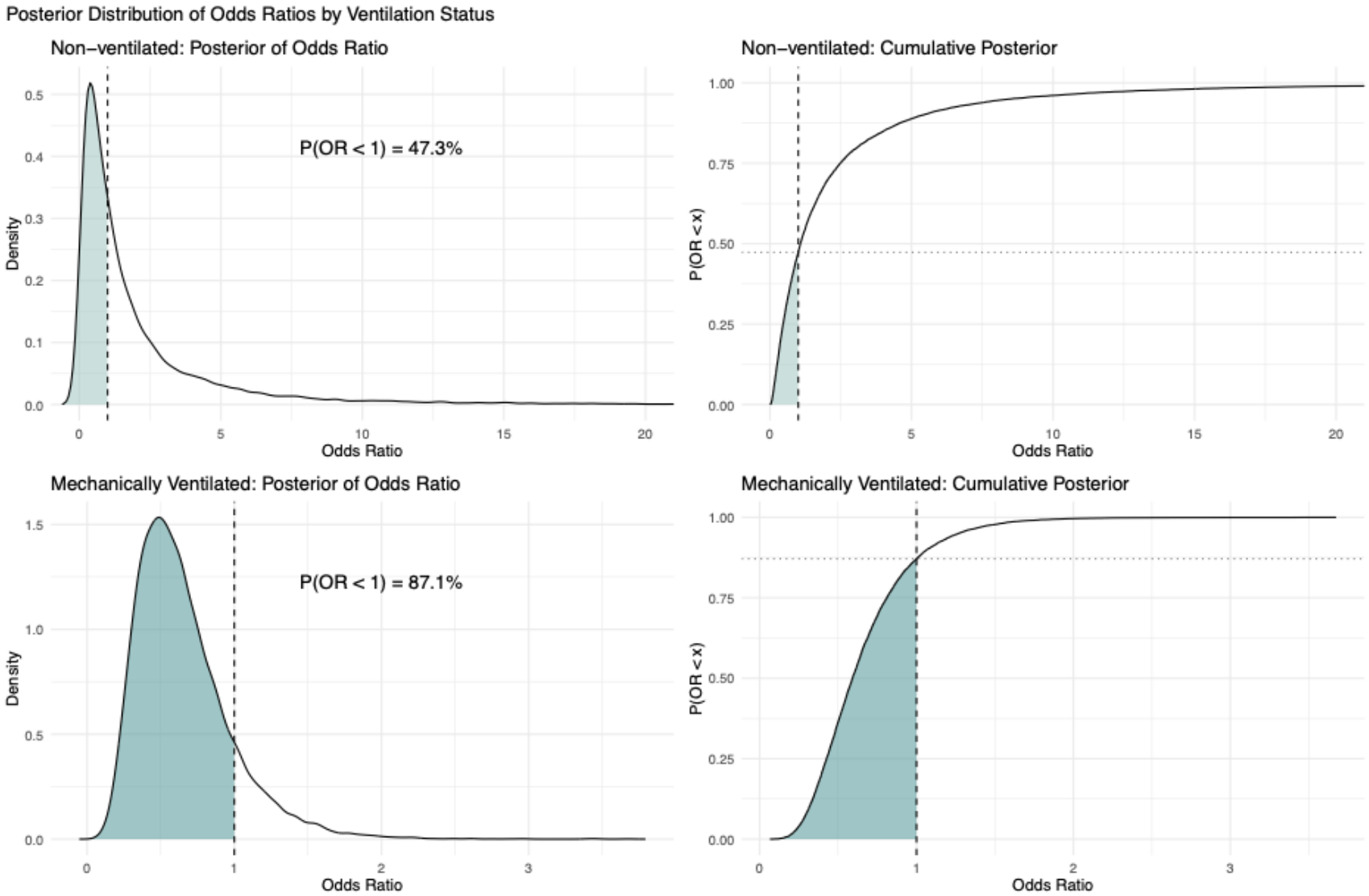
Appendix IV: Supplementary Figure 1. Horizontal bar chart showing the percentage of adherence for each component of the sleep enhancement protocol among patients in the intervention group. Environmental components (e.g., room clock, reduced lighting, alarm volume, door closure, monitor dimming, and promoting daytime wakefulness) achieved 100% adherence. In contrast, lower adherence was observed for patient-dependent components: use of eye masks (67.39%), earplugs (64.35%), and limiting non-essential nighttime procedures (57.09%). The overall adherence rate across all protocol elements was 87.01%.

Appendix V: Supplementary Figure 2. Richards-Campbell Sleep Questionnaire scores across sleep dimensions by treatment group



Appendix IV: Supplementary Figure 2. Distribution of RCSQ scores across all five dimensions—sleep depth (Q1), ability to fall asleep (Q2), number of awakenings (Q3), ability to return to sleep (Q4), and overall sleep quality (Q5)—as well as the total score (RCSQ_All), comparing intervention and control groups. Each plot displays median and interquartile range values. Overlapping distributions suggest no substantial difference in perceived sleep quality between groups.

Appendix V: Supplementary Figure 3. Posterior distribution and cumulative probability for the odds ratio of delirium incidence by baseline mechanical ventilation status.



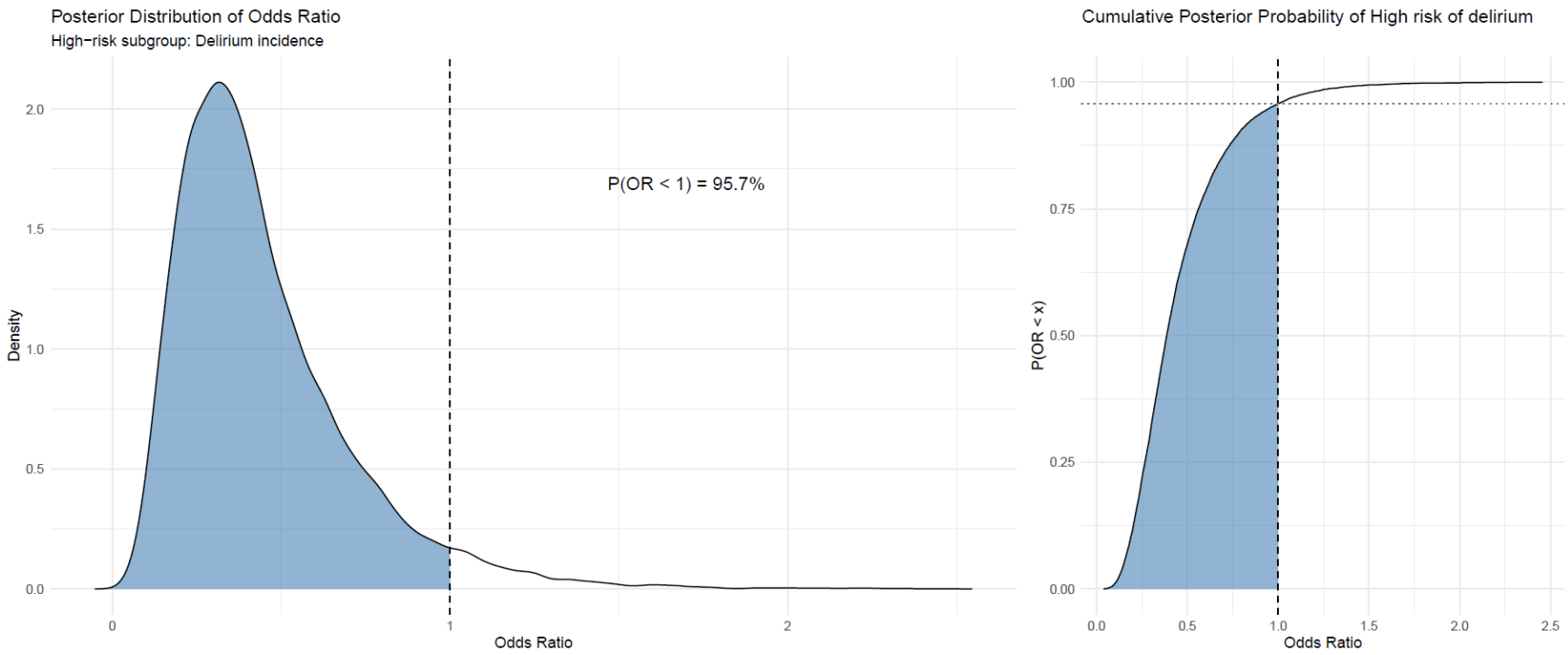
Appendix V: Supplementary Table 2. Subgroup analysis of patients at high risk for postoperative delirium based on predictive score: Outcomes between intervention and control groups with Bayesian effect estimates.

Variables	Intervention (n = 43)	Control (n = 40)	Effect Estimate† (95% CrI)	Probability of Benefit‡
Delirium incidence	6 (14.0%)	12 (30.0%)	0.38 (0.12; 1.83)	95.7%
Delirium characteristics				
Onset (Postoperative day)	2.5 (2.0 – 3.0)	2.0 (2.0 – 3.0)	0.32 (-0.67; 1.34)	73.0%
Duration (days)	3.5 (2.3 – 4.0)	2.0 (1.0 – 2.3)	0.95 (-0.55; 2.69)	13.1%
ICU Delirium-free days	2.0 (1.0 – 3.0)	2.0 (1.0 –3.0)	1.31 (0.70; 2.46)	81.2%
Delirium type				
Hyperactive delirium	5 (11.6%)	6 (15.0%)	4.43 (0.55; 49.02)	8.3%
Hypoactive delirium	0	2 (5.0%)	0.19 (0.01; 3.56)	85.6%
Mixed delirium	1 (2.3%)	4 (10.0%)	0.40 (0.03; 3.49)	78.3%
Antipsychotic treatment	6 (6.7%)	6 (6.8%)	0.92 (0.27; 3.16)	55.6%
Quetiapine dosage (mg)	18.8 (12.5 – 75.0)	37.5 (12.5 – 87.5)	0.85 (0.23; 3.26)	60.5%
Haloperidol dosage (mg)	1.8 (0.0 – 2.5)	0	2.51 (0.07; 24.87)	20.3%
Consequence of delirium				
Self-removal of catheter/ETT	5 (5.6%)	4 (4.6%)	1.19 (0.29; 4.71)	40.4%

Sleep assessment				
RCSQ score (cm)	5.8 (4.8 – 6.8)	5.6 (4.4 – 7.1)	-0.28 (-1.10; 0.53)	25.0%
Question 1: Sleep depth	6.0 (5.0 – 7.0)	6.0 (5.0 – 7.6)	-0.52 (-1.43, 0.40)	13.3%
Question 2: Ability to fall asleep	5.2 (4.6 – 6.9)	5.0 (4.1 – 6.8)	-0.31 (-1.23, 0.61)	25.1%
Question 3: Number of awakenings	5.9 (4.1 – 7.0)	5.0 (4.0 – 7.0)	0.31 (-0.52, 1.15)	76.0%
Question 4: Ability to fall asleep while awake	5.5 (4.4 – 6.6)	5.5 (4.0 – 7.6)	-0.47 (-1.42, 0.47)	16.4%
Question 5: Quality of sleep	6.5 (5.0 – 7.0)	6.6 (5.0 – 8.0)	-0.38 (-1.28, 0.49)	19.8%
Average nighttime noise (dB)	46.5 (44.2 – 49.9)	46.9 (42.1 – 48.9)	1.24 (-0.83; 3.31)	12.0%
Clinical outcomes				
ICU LOS (days)	3.0 (2.0 – 5.0)	2.5 (2.0 – 3.0)	1.63 (1.16; 2.27)	3.0%
Hospital LOS (days)	14.0 (8.5 – 30.0)	13.0 (9.0 – 19.8)	1.01 (0.70; 1.45)	49.0%
ICU mortality	0	0	N/A	N/A
Hospital mortality	6 (14.0%)	2 (5.0%)	2.91 (0.64; 16.96)	9.1%

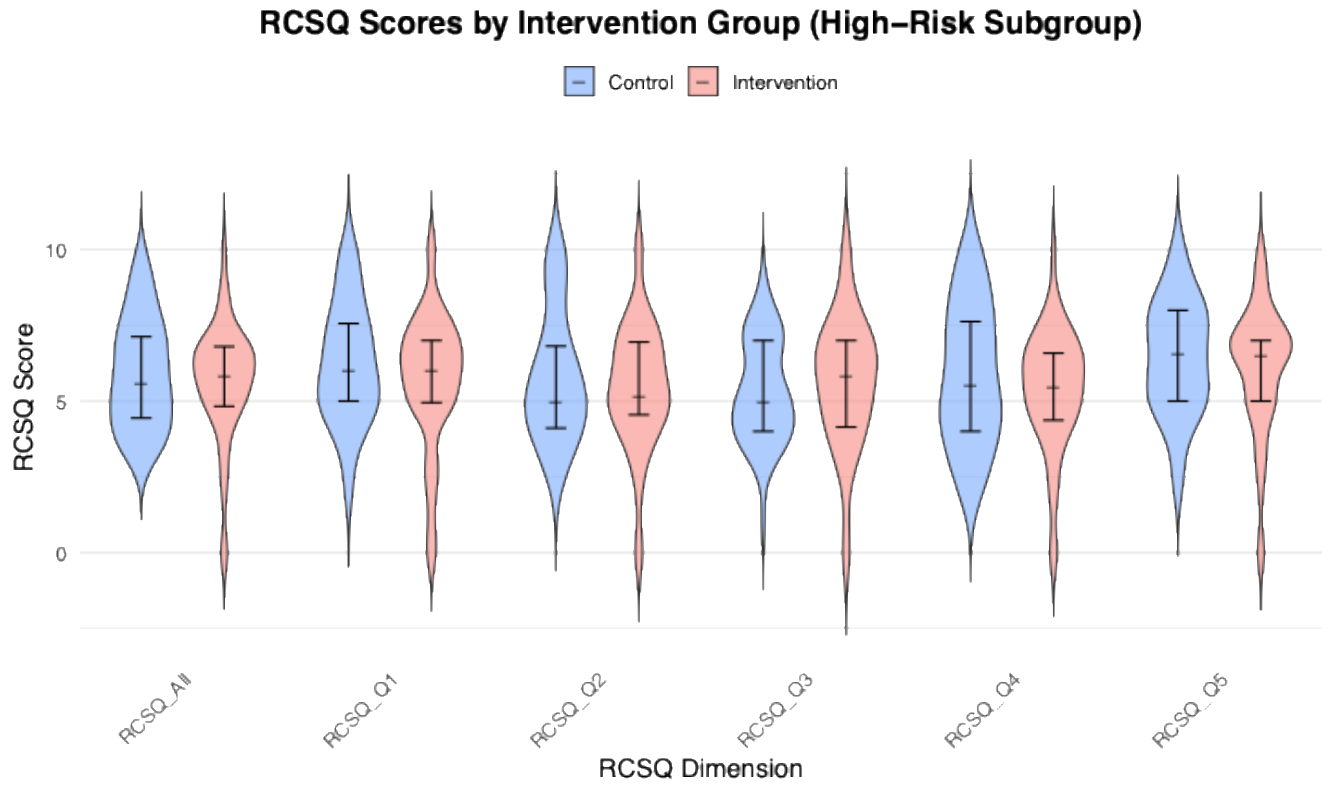
Data are presented as n (%) for categorical variables and median (IQR) for continuous variables. † Bayesian effect estimates were derived from logistic regression for binary outcomes (reported as odds ratios, OR) and generalized linear models (GLMs) for continuous outcomes (reported as median differences, MD). Where applicable, GLMs used distributions such as Gamma with log links, and estimates were back-transformed. All effect estimates are reported with 95% Bayesian credible intervals (CrI). ‡ Probability of benefit was defined as $P(OR < 1)$ for binary outcomes or $P(MD > 0)$ for continuous outcomes, depending on the expected direction of improvement. RCSQ: Richards-Campbell Sleep Questionnaire; ETT: endotracheal tube; dB: decibels; ICU: intensive care unit; LOS: length of stay; N/A: Not applicable or not estimable due to absence of events in both groups.

Appendix V: Supplementary Figure 4. Posterior distribution and cumulative probability for the odds ratio of delirium incidence in high-risk subgroup.



Appendix IV: Supplementary Figure 3 This figure illustrates the posterior distribution (left) and cumulative posterior probability of the odds ratio for delirium incidence in the high-risk subgroup. The vertical dashed line represents an odds ratio (OR) of 1. The shaded area under the curve to the left of the line indicates the probability that OR < 1, which reflects a potential benefit of the sleep enhancement intervention. The estimated posterior probability of benefit was 95.7% in this subgroup, suggesting a directional trend favoring the intervention despite wide uncertainty in the credible interval.

Appendix V: Supplementary Figure 5. Richards-Campbell Sleep Questionnaire scores across sleep dimensions by treatment group in high-risk subgroup.



Appendix III: Supplementary Figure 4. Distribution of Richards-Campbell Sleep Questionnaire (RCSQ) scores for the intervention and control groups across all five dimensions: sleep depth (Q1), ability to fall asleep (Q2), number of awakenings (Q3), ability to return to sleep (Q4), and overall sleep quality (Q5), as well as the total score (RCSQ_All). Each violin and box plots display score distributions, medians, and interquartile ranges, with overlapping distributions suggesting no substantial difference in perceived sleep quality between groups.

Appendix V: Supplementary Table 3. Sensitivity analysis (per-protocol analysis)**:** Baseline demographic and clinical characteristics of surgical critically ill patients.

Patient Characteristics	**Intervention (n = 35)**	**Control (n = 88)**
Age (years)	77.0 (70.5 – 80.5)	75.0 (71.0 – 80.2)
Male	23 (65.7%)	51 (58.0%)
BMI (kg/m^2)	23.2 ± 3.7	23.3 ± 5.4
ASA		
II	3 (8.6%)	13 (14.8%)
III	30 (85.7%)	60 (68.2%)
IV	2 (5.7%)	15 (17.1%)
IQCODE	3.2 (3.1 – 3.6)	3.1 (3.0 – 3.3)
Comorbidities		
Dementia	0	1 (1.1%)
Psychiatric Disease	2 (5.7%)	4 (4.6%)
Stroke	8 (22.9%)	14 (15.9%)
Diabetes	13 (37.1%)	29 (33.0%)
Hypertension	25 (71.4%)	65 (73.9%)
Chronic kidney disease	8 (22.9%)	23 (26.1%)
Cardiac	18 (51.4%)	35 (39.8%)
Cirrhosis	1 (2.9%)	4 (4.6%)
Medication		
Sleep medications	5 (14.3%)	9 (10.2%)
Pain medications	4 (11.4%)	9 (10.2%)
Psychiatric medications	1 (2.9%)	6 (6.8%)
Alcohol consumption	2 (5.7%)	8 (9.1%)
Operation		
Emergency operation	11 (31.4%)	33 (37.5%)

Operation type		
Intra-abdominal surgery	8 (22.9%)	36 (40.9%)
Urologic surgery	6 (17.1%)	11 (12.5%)
Orthopedic surgery	6 (17.1%)	8 (9.1%)
Vascular surgery	12 (34.3%)	24 (27.3%)
Ob-Gyn surgery	1 (2.9%)	1 (1.1%)
ENT surgery	1 (2.9%)	2 (2.3%)
Severity score		
APACHE II	11.0 (9.0 – 15.5)	11.0 (8.0 – 15.3)
SOFA	3.0 (2.0 – 5.0)	3.0 (1.0 – 6.0)
Delirium predictor score		
High risk for delirium[a]	13 (37.1%)	40 (45.5%)
Shock	8 (22.9%)	22 (25.0%)
ICU intervention		
Mechanical ventilation	18 (51.4%)	68 (77.3%)
Ventilator hour(s)	19.5 (15.8 – 38.3)	26.9 (17.5 – 44.6)
ICU event		
Inadequate pain control	16 (45.7%)	48 (54.6%)
Reintubation	0 (0%)	5 (5.7%)
Restraint	4 (11.4%)	19 (21.6%)

Data are presented as n (%) for categorical variables, mean ± standard deviation (SD) or median (IQR) for continuous variables. [a] Defined by a validated delirium risk score (cut-off ≥125), incorporating age, SOFA score, diabetes, benzodiazepine use, mechanical ventilation, and cognitive impairment (IQCODE ≥3.42). BMI: Body mass index; ASA: American Society of Anesthesiologists; IQCODE, Informant Questionnaire on Cognitive Decline in the Elderly; Ob-Gyn: Obstetrics and Gynecologic surgery; ENT: Ear, Nose, and Throat; APACHE II: Acute Physiology and Chronic Health Evaluation II; SOFA: Sequential Organ Failure Assessment; ICU, Intensive Care Unit.

Appendix V: Supplementary Table 4. Sensitivity analysis (per-protocol analysis)**:** Outcomes between intervention and control groups with Bayesian effect estimates.

Variables	**Intervention (n = 35)**	**Control (n = 88)**	**Effect Estimate [a] (95% CrI)**	**Probability of Benefit [b]**
Delirium incidence	2 (5.7%)	15 (17.1%)	0.29 (0.06; 1.12)	96.3%
Delirium characteristics				
Onset (Postoperative day)	2.5 (2.3 – 2.8)	2.0 (2.0 – 2.5)	0.43 (-0.76; 1.65)	77.6%
Duration (days)	2.5 (1.5 – 2.0)	2.0 (1.0 – 2.5)	-0.28 (-2.14; 1.22)	66.3%
ICU Delirium-free days	2.0 (2.0 – 3.3)	2.0 (1.0 – 3.0)	0.18 (-0.24; 0.61)	79.1%
Delirium type				
Hyperactive delirium	2 (5.7%)	9 (10.2%)	1.93 (-1.23; 5.70)	12.5%
Hypoactive delirium	0	2 (2.3%)	-1.15 (-5.25; 2.26)	77.1%
Mixed delirium	0	4 (4.6%)	-1.58 (-5.59; 1.72)	80.3%
Antipsychotic treatment	2 (5.7%)	7 (8.0%)	-0.45 (-2.21; 1.03)	70.1%
Quetiapine dosage (mg)	12.5 (12.5 – 12.5)	25.0 (12.5 – 68.8)	-1.09 (-2.66; 0.99)	89.6%
Haloperidol dosage (mg)	1.0 (1.0 – 1.0)	1.8 (1.4 – 2.1)	-0.36 (-2.20; 2.05)	71.0%
Consequence of delirium				

Self-removal of catheter/ETT	1 (2.9%)	5 (5.7%)	-0.78 (-3.01; 1.00)	77.3%
RCSQ total score (cm)	6.3 (5.0 – 7.1)	5.8 (4.7 – 7.2)	0.05 (-0.71; 0.81)	55.7%
Question 1: Sleep depth	6.0 (5.0 – 7.4)	6.0 (5.0 – 7.8)	-0.04 (-0.88; 0.80)	45.8%
Question 2: Ability to fall asleep	6.0 (5.0 – 7.0)	5.4 (4.4 – 7.6)	0.03 (-0.78; 0.82)	52.6%
Question 3: Number of awakenings	5.9 (4.6 – 7.3)	5.0 (4.0 – 7.0)	0.25 (-0.59; 1.10)	72.3%
Question 4: Ability to fall asleep while awake	6.0 (5.0 – 7.0)	5.9 (4.0 – 7.6)	0.04 (-0.83; 0.91)	53.5%
Question 5: Quality of sleep	6.7 (5.5 – 7.6)	6.6 (5.0 – 8.0)	-0.01 (-0.81; 0.80)	49.6%
Average nighttime noise (dB)	47.0 (43.4 – 50.2)	46.4 (43.1 – 49.2)	-0.36 (-2.64; 1.92)	62.0%
Clinical outcomes				
ICU LOS (days)	2.0 (2.0 – 3.5)	2.0 (2.0 – 3.0)	0.26 (-0.04; 0.56)	4.6%
Hospital LOS (days)	15.0 (10 – 29.0)	13.0 (9.0 – 20.5)	0.22 (-0.08; 0.53)	7.8%
ICU mortality	0	0	N/A	N/A
Hospital mortality	2 (5.7%)	3 (3.4%)	0.38 (-1.50; 2.10)	32.0%

Data are presented as n (%) for categorical variables and median (IQR) for continuous variables. [a] Bayesian effect estimates were derived from logistic regression for binary outcomes (reported as odds ratios, OR) and generalized linear models (GLMs) for continuous outcomes (reported as median differences, MD). Where applicable, GLMs used distributions such as Gamma with log links, and estimates were back-transformed. All effect estimates are reported with 95% Bayesian credible intervals (CrI). [b] Probability of benefit was defined as P(OR < 1) for binary outcomes or P(MD > 0) for continuous outcomes, depending on the expected direction of improvement. RCSQ: Richards-Campbell Sleep Questionnaire; ETT: endotracheal tube; dB: decibels; ICU: intensive care unit; LOS: length of stay; N/A: Not applicable or not estimable due to absence of events in both groups.

Appendix V: Supplementary Figure 6. Sensitivity analysis (per-protocol analysis)**:** Posterior distribution and cumulative probability for the odds ratio of delirium incidence in high-risk subgroup.