Study Protocol, Statistical Analysis Plan, and Informed Consent Form

The Effect of a Virtual Reality Operating Room Tour on Patients' Preoperative Anxiety Level: A Randomised Controlled Trial

DOCUMENT CONTROL

Document date: 12 August 2026 | **Version:** 1.0

Status: Compiled for retrospective upload to ClinicalTrials.gov (study documents / results module).

Note on dates: The *Document date* above is the date this PDF was most recently updated, consistent with the ClinicalTrials.gov *Results Data Element Definitions* ("the date on which the uploaded document was most recently updated and, if needed, approved by a human subjects protection review board"). The date **24 June 2024** shown under "Ethics approval" below is the ethics-committee approval date for protocol no. 2024/398 and is **not** the document date. Enter **12 August 2026** (not 24 June 2024) in the ClinicalTrials.gov Document Date field so that the field, the printed date, and the file metadata agree.

Official title	The Effect of a Virtual Reality Operating Room Tour on Patients' Preoperative Anxiety Level: A Randomised Controlled Trial
Principal investigator	Berceste Kahveci, MSc candidate (Surgical Nursing)
Supervisor	Assoc. Prof. Dr. Nurten Taşdemir
Sponsor	Zonguldak Bülent Ecevit University, Institute of Health Sciences
Study setting	Aydın Adnan Menderes University Training and Research Hospital, Aydın, Türkiye
Study period	10 August 2024 – 10 December 2024
Ethics approval	Aydın Adnan Menderes University Non-Interventional Clinical Research Ethics Committee; protocol no. 2024/398, 24 June 2024
Trial registration	ClinicalTrials.gov – NCT [to be inserted] (retrospective)
Document contents	1. Study Protocol 2. Statistical Analysis Plan 3. Informed Consent Form

Note: This document was compiled from the completed MSc thesis (Zonguldak Bülent Ecevit University, 2025) for retrospective upload to ClinicalTrials.gov. Confirm all bracketed items and reconcile the consent form with the ethics-approved original before use.

Part 1 – Study Protocol

1. Background and Rationale

Preoperative anxiety is common among surgical patients and, when unaddressed, is associated with greater intraoperative anaesthetic requirements, increased postoperative pain and analgesic use, more complications, and slower recovery. Standard preoperative information alone is often insufficient. Immersive virtual reality (VR) enables patients to preview the perioperative environment in a controlled, reassuring way. Evidence for a structured VR operating room tour in adult lumbar disc herniation surgery is limited. This trial evaluated whether a brief, nurse-facilitated VR operating room tour reduces preoperative anxiety in these patients.

2. Objective

To determine the effect of a nurse-facilitated virtual reality operating room tour on the preoperative anxiety level of patients scheduled for lumbar disc herniation surgery.

3. Trial Design

Single-centre, randomised, controlled, pretest–posttest experimental study with two parallel groups allocated 1:1 (29 per group).

Allocation: Randomised. Masking: None (open label). Primary purpose: Supportive care.

4. Study Population and Eligibility

Setting: Neurosurgery Clinic and ICU, Aydın Adnan Menderes University Training and Research Hospital. Of 454 annual admissions, 296 preoperative lumbar disc herniation patients formed the accessible population.

Inclusion criteria:

- Scheduled for lumbar disc herniation surgery
- Aged over 18 and under 65 years
- Agreed to participate
- Able to understand and communicate in Turkish
- Cooperative
- No hearing or perception impairment

Exclusion criteria:

- Under 18 or over 65 years
- Declined to participate
- Unable to understand or communicate in Turkish
- Did not complete the study forms
- In the postoperative period
- Undergoing emergency surgery
- Hearing or perception impairment
- Diagnosis other than lumbar disc herniation

5. Sample Size

Calculated with G*Power 3.1.9.2 at 95% confidence, $\alpha = 0.05$, effect size 0.7495, and power 0.80, yielding 58 participants (29 intervention, 29 control).

6. Randomisation

Randomisation was performed by an independent statistician using the computer-based Research Randomizer program; a random-number table allocated the 58 participants equally to the two groups. The researcher was not involved in allocation. No blinding was applied.

7. Interventions

Intervention group: In addition to standard care, participants viewed an approximately five-minute VR video the night before surgery (at least 12 hours preoperatively), facilitated by the nurse-researcher, using an Oculus Quest 2 headset in a quiet, low-stimulus setting. The video depicted preoperative preparation, transfer to and entry into the operating theatre, the waiting area, the operating room, and the postoperative care area, without images of surgical procedures. Participants could remove the headset if they felt unwell.

Control group: Standard preoperative care only. For ethical reasons, the VR application was offered to the control group after data collection was complete.

8. Outcome Measures

Primary outcome: Surgical anxiety, measured with the Surgical Anxiety Scale for Adult Patients (total score 0–68 and three subscales; higher = greater anxiety; Turkish version Cronbach's alpha 0.890), assessed at baseline (at least one day before surgery) and after the intervention (the night before surgery).

Additional data: Patient Identification/Description Form; and, in the intervention group, self-reported relaxation and willingness to recommend the application.

9. Ethical Considerations

Conducted in accordance with the Declaration of Helsinki. Ethics approval: Aydın Adnan Menderes University Non-Interventional Clinical Research Ethics Committee (no. 2024/398, 24 June 2024); institutional permission from the hospital Chief Physician's Office (no. 587420, 8 August 2024). Written and verbal informed consent was obtained from all participants; written consent was obtained from individuals appearing in the video; permission to use the scale was obtained from its author.

Trial registration statement: Registered retrospectively at ClinicalTrials.gov (NCT [ ]); prospective registration was not mandated by the institution at the time the study commenced (August 2024).

Part 2 – Statistical Analysis Plan

1. Analysis Software and Significance Level

All analyses were performed using IBM SPSS Statistics for Windows, version 25.0. The threshold for statistical significance was set at $p < 0.05$ (two-sided) for all tests.

2. Distribution and Descriptive Statistics

The assumption of normal distribution for quantitative variables was assessed using the Kolmogorov–Smirnov test. Continuous variables are summarised as mean ± standard deviation; categorical variables are summarised as frequency and percentage (%).

3. Primary Analysis

Between-group comparisons (intervention vs control) of surgical anxiety scores were performed using the Mann–Whitney U test.

Within-group comparisons (pretest vs posttest, dependent measures) were performed using the Wilcoxon signed-rank test.

The total score and each of the three subscales of the Surgical Anxiety Scale for Adult Patients were analysed in this manner.

4. Secondary and Group-Comparability Analyses

Associations between groups and categorical variables (e.g. sociodemographic and clinical characteristics) were examined using the chi-square test to confirm baseline comparability of the two groups.

Descriptive statistics were used to summarise intervention-group participants' self-reported relaxation and willingness to recommend the application.

5. Handling of Data and Participants

The target sample of 58 participants (29 per group) was determined a priori by power analysis (see Protocol, Section 5). [State how any missing data, withdrawals, or exclusions were handled and confirm the final analysed sample against the CONSORT flow diagram.]

Part 3 – Informed Consent Form

Reconstruction note: In the thesis the signed consent form (Appendix 3) is included as a scanned image and could not be extracted as text. The version below reconstructs its content from the study details for upload purposes. Replace it with, or verify it against, the ethics-approved original before use.

Title of the Study

The Effect of a Virtual Reality Operating Room Tour on Patients' Preoperative Anxiety Level: A Randomised Controlled Trial

Invitation and Purpose

You are invited to take part in a research study. The purpose of this study is to examine the effect of a short virtual reality (VR) tour of the operating room, delivered by a nurse the night before surgery, on the anxiety experienced by patients before lumbar disc herniation surgery. Please read the information below and ask any questions before deciding whether to take part.

What Participation Involves

If you agree to participate, you will be assigned by chance (like the toss of a coin) to one of two groups. One group watches an approximately five-minute VR video showing preoperative preparation and the operating room environment, using a VR headset, the night before surgery. The other group receives the standard preoperative care given to all patients. All participants will complete a short personal information form and a surgical anxiety questionnaire before and after this period. The video does not contain any images of surgical procedures.

Possible Risks and Benefits

The VR application is non-invasive. Rarely, some people may feel mild dizziness, nausea, or headache while using a VR headset; if this happens, you may remove the headset and stop at any time. The study may help reduce preoperative anxiety and may contribute to improving perioperative nursing care. Participants in the standard-care group will be offered the VR application after data collection is complete.

Voluntary Participation and Withdrawal

Your participation is entirely voluntary. You may decline to participate or withdraw at any time without giving a reason. Your decision will not affect your medical care or your relationship with your healthcare providers in any way.

Confidentiality

Your personal information will be kept confidential and used only for scientific purposes. Your identity will not be disclosed in any report or publication arising from this study.

Contact

For any questions about the study you may contact: Berceste Kahveci (Principal Investigator) / Assoc. Prof. Dr. Nurten Taşdemir (Supervisor), Zonguldak Bülent Ecevit University. [Add contact details as required by the ethics committee.]

Statement of Consent

I have read and understood the information above. I have had the opportunity to ask questions, and my questions have been answered. I understand that my participation is voluntary and that I may withdraw at any time. I voluntarily agree to take part in this study.

Participant name / signature / date _____

Researcher name / signature / date _____