Official Title of the Study:

The Effectiveness of Virtual Reality Distraction on Preoperative Anxiety in Abdominal Surgery Patients: A Double-Blinded Randomized Controlled Trial

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Study Protocol and Statistical Analysis Plan

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Sponsor:

Trakya University

Study Site:

General Surgery Service, Trakya University Hospital, Edirne, Türkiye

Confidentiality Statement:

Study Protocol and Statistical Analysis Plan

1.Study Title

The Effectiveness of Virtual Reality Distraction on Preoperative Anxiety in Abdominal

Surgery Patients: A Double-Blinded Randomized Controlled Trial

2. Study Protocol

2.1 Aim

This study aimed to evaluate the effectiveness of virtual reality (VR) distraction in alleviating preoperative anxiety among patients scheduled for abdominal surgery

2.2 Design

This is a double-blinded (blinded to data collection and data analysis) randomized controlled trial conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The study protocol is registered at ClinicalTrials.gov (ID: NCT05718661).

2.3 Study Setting and Period

The study was conducted between December 1, 2022, and December 20, 2024, at the General Surgery Service of a university hospital in the Trakya region, Edirne, Türkiye. The hospital serves as a referral center and contributes to medical and health sciences education.

2.4 Participants

Inclusion Criteria:

- Adults aged ≥18 years
- Undergoing elective abdominal surgery (e.g., appendectomy, hernia, gallbladder/pancreas surgery)
- Awaiting transfer to the operating room in the morning
- Able to communicate and provide informed consent

Exclusion Criteria:

- Abdominal cancer surgery
- Emergency or unplanned surgery
- Isolation status
- Visual/auditory impairments
- Neurological disorders (e.g., vertigo)

2.5.Sample Size

The sample size was calculated based on the study by Mosso et al. (2009) using G*Power 3.1.9.7 software. With an effect size of d=0.920, alpha=0.05, and power=0.95, a total of 96 patients were required (32 in each group).

2.6 Randomization

Patients were randomized using the Research Randomizer tool (https://www.randomizer.org/) into three groups: VR, placebo-video, and control.

3.Interventions and Data Collection

3.1 Tools

Patient Information Form: Sociodemographic and clinical data.

Visual Analog Scale-Anxiety (VAS-A): Scores from 0 (no anxiety) to 10 (maximum anxiety).

Smart Bracelet (Xiaomi Mi Band 5): Measures heart rate variability-based stress (1100 scale).

3.2.Procedures

Evaluation 1 (T1):

-Conducted in the patient's room in the morning.

-Informed consent obtained; forms and baseline anxiety/stress measurements completed.

Evaluation 2 (T2):

-Conducted 10–15 minutes after intervention or rest period

Virtual Reality Group:
-Watched a 2-hour 4K virtual forest video
(https://www.youtube.com/watch?v=uEMmpJgaXvo).
-Used Zore G04E VR Shinecon headset with headphones and disposable eye covers.
-The researcher observed for any adverse effects.

Placebo-Video Group:

Watched the same video on a smartphone using disposable headphones

Control Group
No intervention; second evaluation conducted after ~15 minutes of rest.

4.Ethical Considerations
Approval was obtained from the Trakya University Ethics Committee (TÜTF-GOBAEK 2022/240) and the hospital administration (E-51088030-100-317619). All participants provided verbal and written informed consent. The study adhered to the Helsinki Declaration and CONSORT guidelines
5.Statistical Analysis Plan

5.1.Software

Data analysis was performed using IBM SPSS Statistics for Windows, Version 28.0

5.2.Descriptive Statistics

-Continuous variables (e.g., age, anxiety, stress): Mean, SD, median, min, max

-Categorical variables (e.g., gender, education, chronic diseases): Frequency and percentage

5.3.Normality Testing

Shapiro-Wilk test for all continuous variables

5.4.Inferential Statistics:

-Between-Group Comparisons:

Kruskal-Wallis H Test for comparing continuous variables across the three groups

Mann-Whitney U Test with Bonferroni correction for post-hoc pairwise comparisons

-Within-Group Comparisons (T1 vs. T2):

Wilcoxon Signed Ranks Test

-Categorical Variables:

Pearson Chi-Square Test

5.5.Statistical Significance

Significance level set at $p < 0.05$

Confidence interval: 95%