Official Title of the Study: ***Effect of Video-Assisted Online Preoperative Education on Fear, Anxiety, Sleep and Stress in Patients Undergoing Laparoscopic Cholecystectomy: Randomized Controlled Study***

NCT Number: ***Not yet assigned at time of submission***

Date of the Document: ***February 10, 2025***

Aim : The overall objective of this study was to examine the effects of online preoperative education on fear, anxiety, sleep patterns, and stress levels in patients undergoing laparoscopic cholecystectomy. The aim was to assess the potential ameliorative effects of online education on these negative emotional states by improving patients' understanding of the surgical process and their sense of security.

Ethical Aspects of the Research

Before initiating the research, the subject was approved by the Hasan Kalyoncu Graduate Institute Ethics Committee (Approval No: 2024/5).

Before initiating the research, permission was obtained from the Bingöl University Rectorate Health Sciences Scientific Research and Publication Ethics Committee (Ethics Approval No: E-33117789-044-171830). Additionally, permission was obtained from the Harran University Clinical Research Ethics Committee (Ethics Approval No: HRÜ/25.03.49).

Institutional permission was also obtained from the Bingöl Provincial Health Directorate where the research would be conducted (Approval No: E-45082128-105.05.04-254841450).

Written permission was obtained from the authors who adapted the Surgical Fear Scale (SFS), Visual Comparison Scale (VCS), and Richards Champell Sleep Scale (RCS) into Turkish and conducted their validity and reliability studies. Patients will be informed about the study both verbally and in writing (Emanuel EJ 2004). All stages of the study will be conducted in accordance with the ethical principles outlined in the World Medical Association Declaration of Helsinki (WMA Helsinki).

Research Type, Location, and Timeframe

The study will be a randomized controlled clinical trial conducted in the general surgery ward of Bingöl State Hospital.

Research Population and Sample

The study will consist of patients presenting to the general surgery ward of Bingöl State Hospital. The study sample will consist of patients who volunteered to participate in the study (N: 128).

The G* Power 3.1.9.7 program was used to calculate the sample size. A pyrrho calculation was performed, assuming that an independent samples t-test could be used to compare the scale scores (RCU-GKÖ-CÖ) between groups. Cohen's d (standard effect size) was used in the calculation (Cohen J 1998). Based on the two-sided hypothesis, a medium effect size of 0.05, an α error of 0.05, a ß error of 0.20, and a power of 80%, the minimum sample size for each group was determined to be 128 (N=128) for the intervention group (n=64), the control group (n=64), and the total sample size. Following completion of the study, a post hoc calculation will be conducted to retest the adequacy of the sample size.

Research Implementation

Research data will be collected by three nurses working on the ward where the study is conducted. The primary purpose of having these three nurses collect the data is to ensure

that the measurements are carried out in a standardized, reliable, and unbiased manner. Because the researchers were responsible for planning and implementing the intervention in the study, they intentionally withdrew from the data collection process. This prevented the observer effect and limited the data collectors' access to group information by ensuring single-blindness. The three nurses who will participate in the data collection process will receive a standardized training process in advance regarding the scales to be used, measurement times, and biochemical data collection protocol, thus strengthening inter-measurement consistency and internal validity.

Statistical Analysis of Data

Statistical analysis of the data will be performed using IBM SPSS 27.0 (IBM SPSS Inc., USA) for Windows. For descriptive statistics, number (n) and percentage (%) will be used for discrete values, and the mean ± standard deviation will be used for continuous numerical values. Data will be screened using the Kolmogorov-Simirnov and Shapiro-Wilk tests to determine whether the data are normally distributed. The independent samples t-test will be used to compare means of variables with a normal distribution ($p>0.05$), and the Mann-Whitney U test will be used to compare means of variables with a non-normal distribution ($p<0.05$). The Chi-Square test will be used for discrete variables. A $p<0.05$ value will be accepted for statistical significance.