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Study Protocol / Araştırma Protokolü

The Effect of Patient Education and in the Operating Room Family Interview Practices on Patient Outcomes Using Virtual Reality Glasses in Cholecystectomy Patients: A Randomized Controlled Trial Protocol

Kolesistektomi Hastalarında Sanal Gerçeklik Gözlüğü Kullanılarak Hasta Eğitimi ve Ameliyathanede Aile Görüşmesi Uygulamalarının Hasta Sonuçlarına Etkisi: Randomize Kontrollü Çalışma Protokolü

Çağla ISLATTI MUTLU[1]

Yasemin ERGÜN[2]

[1]Arş. Gör., Marmara Üniversitesi, Sağlık Bilimleri Fakültesi, Hemşirelik Bölümü, Hemşirelikte Yönetim Anabilim Dalı, İstanbul, Türkiye.

[2]Dr. Öğr. Üyesi, Marmara Üniversitesi, Sağlık Bilimleri Fakültesi, Hemşirelik Bölümü, Hemşirelikte Yönetim Anabilim Dalı, İstanbul, Türkiye.

Yazışmadan sorumlu yazar: Çağla Islattı Mutlu; caglaislatti@gmail.com

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Abstract:
Aim: This study aims to determine the effect of patient education and in the operating room family interview practices using virtual reality glasses on patient outcomes related to stress, anxiety and information need, sleep quality and satisfaction with the preparation for surgery in cholecystectomy patients.
Methods: The study was designed as a randomized controlled experimental study. There are three groups with equal numbers of participants randomly assigned. The sample of the study will consist of 60 patients scheduled for laparoscopic cholecystectomy in the general surgery ward of a training and research hospital in Turkey. The first group will receive patient education with virtual reality(VR) glasses in the ward before surgery(n=20), the second group will receive patient education with VR glasses in the ward and family interview with VR glasses in the operating room before surgery(n=20), and the third group will receive no intervention(n=20). Stress and satisfaction of the patients will be assessed by visual analog scale, anxiety and information need by Amsterdam preoperative anxiety and information scale(APAIS), sleep quality by Richard-Campbell sleep scale(RCSS).
Results: Data collection started in January 2025. The researcher continues to collect data.
Conclusion: This trial will provide valuable evidence that offers technological approaches to clinical practice by evaluating the effects of interventions.
Trial registration: This trial was registered in October, 2024(NCT06634615).

Key Words: Virtual reality; anxiety; sleep; satisfaction; cholecystectomy.

Özet:
Giriş: Bu çalışma, kolesistektomi hastalarında sanal gerçeklik gözlüğü kullanılarak hasta eğitimi ve ameliyathanede aile görüşmesi uygulamalarının stres, anksiyete ve bilgi ihtiyacı, uyku kalitesi ve ameliyata hazırlık sürecinden memnuniyete yönelik hasta sonuçları üzerine etkisini belirlemeyi amaçlamaktadır.
Yöntem: Araştırma, randomize kontrollü deneysel çalışma türünde tasarlanmıştır. Rastgele atanmış eşit sayıda katılımcının olduğu üç grup bulunmaktadır. Çalışmanın örneklemini Türkiye'deki bir eğitim ve araştırma hastanesinin genel cerrahi servisinde laparoskopik kolesistektomi planlanan 60 hasta oluşturacaktır. İlk gruba ameliyat öncesi serviste sanal gerçeklik gözlüğüyle (VR) hasta eğitimi(n=20), ikinci gruba ameliyat öncesi serviste VR hasta eğitimiyle birlikte ameliyathanede VR aile görüşmesi(n=20) uygulanacak ve üçüncü gruba herhangi bir müdahale yapılmayacaktır(n=20). Hastaların stres ve memnuniyeti görsel analog skala, anksiyete ve bilgi ihtiyacı Amsterdam preoperatif anksiyete ve bilgi ölçeği, uyku kalitesi Richard-Campbell uyku ölçeği ile değerlendirilecektir.
Bulgular: Veri toplama Ocak 2025'te başlamıştır. Araştırmacı veri toplamaya devam etmektedir.
Sonuç: Bu çalışma, müdahalelerin etkilerini değerlendirerek klinik uygulamaya teknolojik yaklaşımlar sunan değerli kanıtlar sağlayacaktır.
Deneysel çalışma kayıt: Bu deneme Ekim 2024'te kaydedildi (NCT06634615).

Anahtar Kelimeler: Sanal gerçeklik; anksiyete; uyku; memnuniyet; kolesistektomi.

Introduction

Laparoscopic cholecystectomy is recognized as the first treatment of choice for surgical removal of the gallbladder.[1] According to the National Healthcare Associated Infections Surveillance Network report, 85.727 gallbladder surgeries were performed in Türkiye in 2023 and this is one of the most frequently performed operations.[2] Surgeries are one of the medical procedures that cause patients to perceive under a physical constraint, are life-threatening, and can cause anxiety and stress.[3] It is known that the patient's sleep quality deteriorates in the postoperative period.[4]

Between 25.00% and 80.00% of patients experience preoperative anxiety, which peaks on the way to the operating room.[5] A meta-analysis shows that approximately one in two patients undergoing surgery in low- and middle-income countries experience preoperative anxiety.[3] In addition, perioperative anxiety causes stress in patients and is closely associated with postoperative complications.[5,6] These include increased analgesic drug consumption and acute pain intensity, changes in vital signs and arrhythmias, increased morbidity, prolonged recovery and hospitalization, and poor sleep quality.[3,5,7-9] There are studies showing that patients with preoperative anxiety have worse perioperative sleep quality than patients without anxiety, and even 2.53 times more likely to have poor sleep quality after surgery.[10,11] In addition, postoperative sleep deprivation decreases patients' satisfaction. Accordingly, controlling preoperative stress and anxiety is a critical factor in improving postoperative sleep quality.[12]

The ERAS protocol requires the patient to be informed in the preoperative period. The patient will experience less anxiety by taking an active role in care.[13,14] When information is provided in written, visual or short videos, it is thought to be more effective on surgical anxiety.[15] In addition, in the study describing the perioperative experiences of patients, themes such as the feeling of not being treated as an individual while waiting for surgery and the benefit of having a caregiver/relative with them in the preoperative waiting area were identified.[16] It also shows that most of them feel lonely in the pre-operative phase and that emotional support is very important.[17] Patients complain about the preoperative waiting environment and lack of information and ask for extra calming agents.[18] Since all these will affect the patient's anxiety, stress, sleep and satisfaction levels, supportive practices are necessary. More research is needed to address the effective use of non-drug therapies in the preoperative period.[12] In this context, easy-to-use, inexpensive, effective, non-pharmacologic and technological virtual reality applications come to the fore.

Virtual reality (VR) enables people to experience the sensation of entering a virtual and digital world by producing interactive three-dimensional sensory experiences such as sight, touch and hearing.[19] It is a state of exposure that allows the individual to feel the virtual environment as real.[20] Although the foundations of virtual reality technologies date back to the 1960s, they have entered daily use with the significant developments in technology in recent years. It has become popular and widespread with various applications ranging from entertainment to education, health to defense.[21,22] VR technology is a feasible and acceptable intervention method that plays an important role in alleviating health problems.[19] It shows that patients move away from the hospital environment by experiencing a strong sense of being there.[23] With VR applications, patients reported lower anxiety and fear, better procedure understanding, and high satisfaction.[5,23] In addition, there are almost no studies in the literature involving VR family interviewing. Well-designed studies are needed to evaluate a new intervention that supports the clinical field. In this direction, this study is important as it is the first study that includes VR patient education and VR family interview intervention in the operating room together and it forms the basis for future studies.

Aim

The study aims to determine the effect of patient education and in the operating room family interview practices using virtual reality glasses on patient outcomes related to stress, anxiety and information need, sleep quality and satisfaction with the preparation for surgery in cholecystectomy patients.

Hypotheses

The research hypotheses are as follows:

H1: There is a significant difference in the levels of stress, anxiety, and information need between patients who received virtual reality patient education in the ward before cholecystectomy surgery and those who did not.

H2: There is a significant difference in stress and anxiety levels between patients who did and did not have a virtual reality video family interview in the preoperative waiting area before cholecystectomy surgery.

H3: There is a significant difference in the levels of stress, anxiety and sleep quality at discharge in the groups that received different virtual reality interventions.

H4: Patients who underwent virtual reality have a high level of satisfaction with the preparation process for surgery.

Materials and Methods

Trial Design

This study was designed as a randomized controlled experimental study. There are three groups with equal numbers of participants randomly assigned.

CONSORT(2010) and SPIRIT(2013) checklists followed to ensure comprehensive reporting throughout the study.

Study Setting

It is performed in the 20-bed general surgery service and operating room (OR) preoperative waiting room of a training and research hospital, Istanbul, Türkiye. Patients are admitted to the ward one day before surgery. Patients are hospitalized one day before the operation. After the operation is completed, they return to the ward and are discharged the next day.

Eligibility Criteria

Inclusion criteria were that the patient was 18 years of age or older, planned to elective laparoscopic cholecystectomy, had no visual, hearing or communication problems, accepted voluntary participation in the study, had a smartphone and internet connection, and had a stress intensity higher than 3 points (between 1-10 points). Exclusion criteria were that the patient had complaints of dizziness, psychiatric disorders, persistent sleep problems, and any allergy to the eyeglass material. Exclusion criteria included patients leaving the study voluntarily, interrupting the family video call with VR, feeling uncomfortable during VR, and incomplete and/or incorrect completion of the data collection forms.

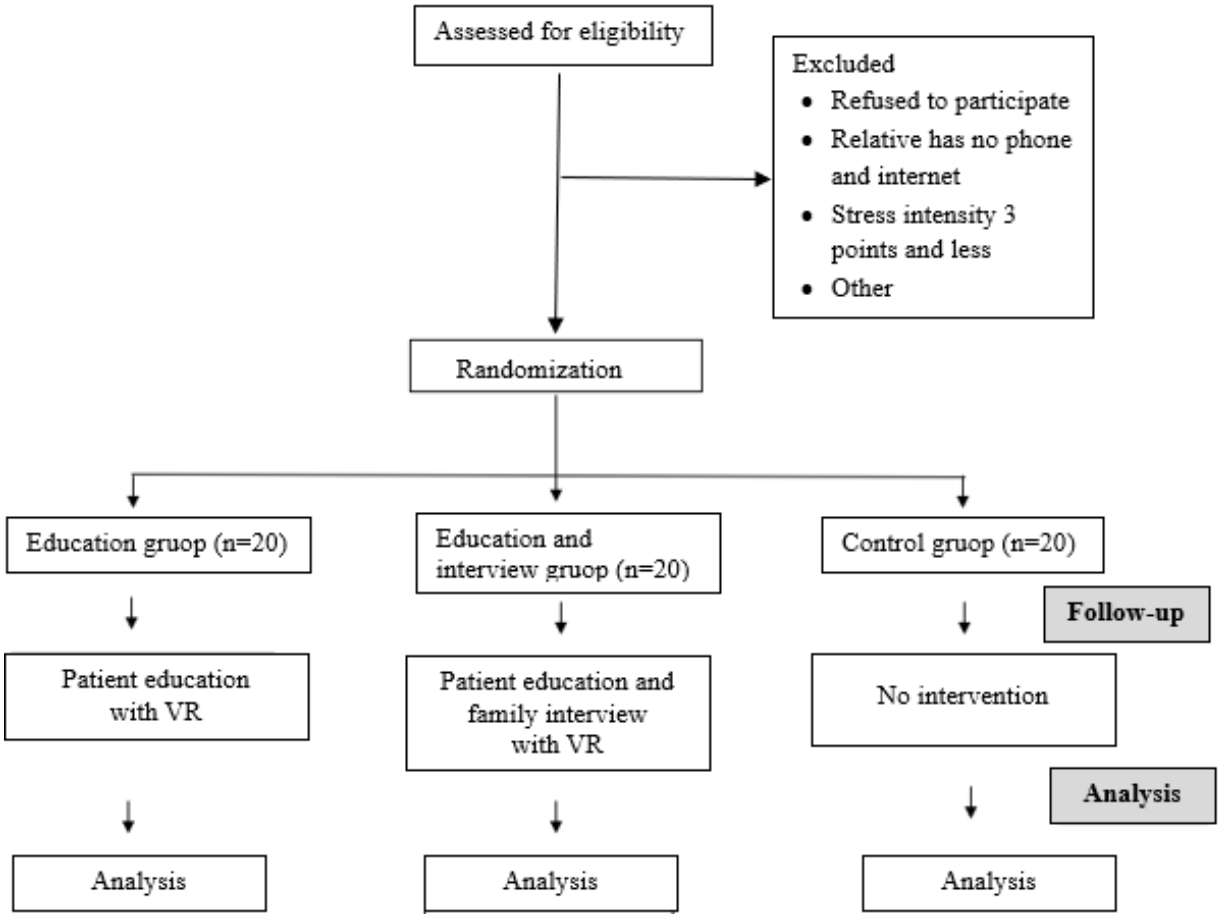

Figure 1. Study Flowchart According to CONSORT.

Interventions

Patients are sorted according to the time of hospitalization. They are assigned to education, education and interview, and control groups according to the randomization list. Patients are invited to the study and their informed consent is obtained. Face-to-face communication is established with each patient in the ward on the day of hospitalization, in the preoperative waiting area when they come to the operating room and in the ward on the day of discharge. After hospitalization, participants assigned to the education and, education and interview groups are shown a 5-minute animated training video with visual and auditory elements in the patient room using virtual reality glasses. In addition, participants in the education and interview group are provided with a 5-minute video family interview with virtual reality glasses in the preoperative waiting area of the OR. The service routine continues for the control group and no intervention is made (Figure 1).

The content of the training video includes the concept of cholecystectomy, the reasons for removal of the gallbladder, how laparoscopic cholecystectomy is performed, the advantages of laparoscopic surgery compared to open surgery, the preoperative and day of surgery

preparation process, the conditions to be followed after surgery, the importance of nutrition and fluid intake, defecation, the importance of early mobilization and discharge.[1,4,24-29]

The virtual family interview is conducted using Oculus Quest 2(Meta Technologies LLC, USA) virtual reality glasses. The interview starts through the meeting link shared with the patient's relatives, and the BigScreen computer application provides VR glasses and computer connection. Patients have a video call with their family in a 360° designed home environment.

Outcomes

The primary outcomes are stress, anxiety, sleep quality and satisfaction with the preparation for surgery. Secondary outcomes are level of information needs and virtual reality assessment.

Tablo 1. Participant Timeline

Time / Instruments	Hospitalization/ admission	After admission or education	Preoperative waiting area	Before going to surgery	Before discharge
Informed consent form	X-Y-Z				
Descriptive information form	X-Y-Z				
Visual analog scale for stress	X-Y-Z	X-Y-Z	X-Y-Z	X-Y-Z	X-Y-Z
APAIS	X-Y-Z	X-Y-Z	X-Y-Z	X-Y-Z	X-Y-Z
RCSS	X-Y-Z				X-Y-Z
Visual analog scale for satisfaction					X-Y-Z
Virtual reality assessment form					X-Y

Groups; Education: X, Education and Interview: Y, Control: Z

Participant Timeline

The use of virtual reality glasses is explained to the intervention groups. Contact information of the relatives of the patients who will have a VR family interview is obtained. Relatives are contacted and informed about participation in the virtual reality video family interview. During the research process, participants are evaluated with the following measurements (Table 1):

1. Groups, in the ward on the day of hospitalization;
    a. Descriptive information form, visual analog scale (VAS) for stress, APAIS and RCSS
    b. Education and, education and interview groups watch VR education video and the control is not intervened.
    c. After 30 minutes[30], the VAS for stress and APAIS
2. When the OR is taken to the preoperative waiting area;

a. VAS for stress and APAIS
b. Conducts a 5-minute[31] VR family interview for the education and interview group. The education and control groups are not intervened.
c. At the end of the waiting period, the VAS for stress and APAIS

3. Pre-discharge in the ward;
   a. VAS for stress, APAIS, RCSS and VAS for satisfaction
   b. VR assessment form in addition to the intervention groups.

Sample Size

The sample size in the study was calculated with G*Power(v3.1.9.7) power analysis program. Based on the preoperative post-test mean anxiety scores(VR distraction: 34.97±11.37; VR training: 32.61±9.88 Control: 55.21±20.01)[30], it was determined that the effect size d=0.71 in the calculation made with three groups to obtain 95.00% power at α=0.05 level and at least 12 patients in each group and 36 patients in total should be included in the study. Considering the possible losses, it was decided to include a total of 60 patients, 20 patients in each group.

Recruitment and Allocation

In the study, a randomization list prepared with a random sequence generator(www.random.org) will be used to determine the groups in which patients will be included. Patients are sorted according to the time of hospitalization and the randomization list is used to determine which group they are in.

Blinding

Due to the nature of the application method to be used, the researcher and patients will not be blinded. The statistician will be blinded in the analysis of the study.

Data Collection

Data collection started in January 2025. The researcher continues to collect data.

Instruments

In the study, data will be collected with an descriptive information form, VAS for stress, APAIS, RCSS, VAS for satisfaction and VR assessment form. Oculus Quest 2 VR glasses will be used as a virtual reality application tool in the study.

Descriptive information form

The descriptive information form was created by reviewing the literature[23,32-34] consists of two parts. In the first part, there are four questions about individual characteristics including age, gender, educational status and marital status, and in the second part, there are 11 questions about the presence of chronic diseases, hospitalization, anesthesia and surgery experience, sleep

problems and medication use, number of surgeries, change of surgery day, discomfort, cholecystectomy knowledge, and a total of 15 questions.

Visual analog scale (VAS) for stress

It is a scale ranging from 0-not at all stressed to 10-very stressed on a 10 cm ruler to assess the stress intensity of the patients. As the scale goes from 0 to 10, the stress level increases. This scale is a valid and reliable tool for measuring stress level.[35,36]

Amsterdam preoperative anxiety and information scale (APAIS)

The APAIS was developed by Moerman et al.(1996) and adapted into Turkish by Çetinkaya et al.(2019).[37,38] The scale, which was developed to assess preoperative anxiety and information needs of adult patients, consists of 2 subscales and 6 items. There are 4 items representing the fear of anesthesia and surgical procedure in the anxiety subscale and 2 items in the information need subscale. The scale is a 5-point Likert scale and is scored from 1-"Not at all" to 5-"Extremely". The score ranges of the anxiety subscale and information need subscale are 4-20 and 2-10, respectively. Total scale score is min. 6 and max. 30. High scores are associated with high anxiety level and need for information. There are no reverse items in the scales. In the original version, the Cronbach's alpha coefficient of the anxiety scale was 0.86 and the information need scale was 0.72. In the Turkish version, the scale showed a high level of validity and reliability with anxiety α=0.89, information need α=0.78 and total α=0.87.

Richard-Campbell sleep scale (RCSS)

The RCSS was developed by Richards(1987) and adapted into Turkish by Karaman Özlü and Özer(2015). This scale consists of six items. Each item is answered on a scale from 0 to 100. A score between "0-25" indicates very poor sleep and a score between "76-100" indicates very good sleep. The item evaluating the noise level in the environment is not included in the total score calculation and is calculated over five items. As the score obtained from the scale increases, sleep quality also increases. While the Cronbach's α value of the original scale was 0.82, the Turkish version was 0.91.[39]

Virtual reality assessment form

This form consists of six questions about the features related to the VR application, including past VR experience, comfort of using VR glasses, feeling discomfort in the application, wanting to use the VR application again, recommending the VR application to others, and thoughts about the VR application experience.[23,32-34]

Visual analog scale for satisfaction

It is a scale ranging from 0-not at all satisfied to 10-very satisfied on a 10 cm ruler to assess patients' satisfaction with the preparation for surgery.[36,40] As the scale goes from 0 to 10, the satisfaction level increases. The individual determines his/her satisfaction level by considering all the components of the preparation for surgery in the hospital and marks the corresponding score on the line. This scale is a valid and reliable tool for measuring satisfaction level.

Data Management

The principal researcher will ensure that all data are coded and entered into the statistical analysis program accurately and completely. Informed consent forms and the original printed versions of the data collection tools will be kept confidential and stored by the researchers. Researchers will have access to the data.

Statistical Methods

IBM Statistical Package for Social Science (SPSS, version 22) statistical software will be used for statistical analyses. While evaluating the study data, descriptive statistical methods(mean, standard deviation, frequency), Student T test and ANOVA test will be used for the comparison of quantitative data in parameters with normal distribution. Mann Whitney U test and Kruskal Wallis test will be used in comparisons of non-normally distributed parameters. Dependent T test, Paired Sample T test and Wilcoxon Signed Rank test will be used for intra-group comparisons. Correlation analyses will be used to examine the relationships between the parameters. Cronbach's alpha coefficient will be calculated for scale reliability. Significance will be evaluated at $p<0.05$ level.

Data Monitoring

For the applicability of the data collection process, comprehensibility and usability of the forms, a total of six patients, two from the education group, two from the education and interview group and two from the control group, will be included in the pilot study. These patients will not be included in the trial. All data to be obtained during the study will be monitored.

Harms

Unintended and unexpected effects reported or observed by participants will be recorded. Relevance to intervention applied will be monitored by the researchers.

Auditing

Each stage of the trial will be supervised by the researchers. Participants' adaptation with the research will be ensured. Oculus Quest 2 (Meta Technologies LLC, USA) virtual reality glasses and computer were provided by the principal researcher. Experts in the field were consulted for the transformation of educational information into a video form with visual and auditory elements in animation style.

Ethics

The study was approved by Marmara University Faculty of Medicine, Pharmaceutical and Non-Medical Device Research Ethics Committee (date: 14.06.2024, decision no: 09.2024.646). Research permission was obtained from the Istanbul Provincial Health Directorate (date: 13.11.2024, decision no: 2024/17). Written informed consent was obtained from the participants who voluntarily agreed to participate in the research. In this trial, permission for the use of the APAIS and RCSS were obtained from the authors who adapted it into Turkish. During the study, the principles of the Declaration of Helsinki and and the Good Clinical Practice Guidelines were followed. This trial registration was established at ClinicalTrials.gov (NCT06634615).

Dissemination Policy

Research results will be disseminated through presentations at national or international academic congresses/symposia and/or publications in international refereed scientific journals.

Discussion

Surgical procedures are frightening medical procedures for patients, accompanied by physical and psychological elements, uncertainty and unknown. Anxiety and stress are the most common factors and negatively affect sleep status in the postop period, which reduces the quality of life and comfort of patients.[4,9] It also causes postoperative complications, prolonged recovery and hospitalization, loss of labor and increased workload of healthcare professionals.[6,41] Keeping these at a moderate level is one of the goals of primary periop nursing care and supportive practices are needed in the preoperative period.[42] Patient education with virtual reality glasses, one of the interventions to be implemented in this study, will enable the patient to understand and apply the process more easily in the preoperative period with animated video. The other intervention of the study, family interview with virtual reality glasses, will enable the patient to feel safe in the preop waiting area of the OR thanks to family communication and to find himself in a different area and experience by moving away from his environment. It is thought that all of these will reduce the level of anxiety and stress experienced

by the patient in the preoperative process, improve sleep quality and ensure satisfaction with the preparation process for surgery. It will also provide a different example of providing education and family togetherness, which are among the basic roles and responsibilities of health professionals. The inclusion of technological developments in clinical practice may contribute to non-pharmacologic applications and future scientific studies.

Results and Recommendations

This study will evaluate the effect of patient education and family interview with virtual reality glasses on patient outcomes in preparation for laparoscopic cholecystectomy surgery. It will make valuable contributions to the literature by providing patient follow-up in different environments such as the ward and operating room and in both preoperative and postoperative processes.

Limitation

The limitations of the study include the necessity of internet connection in VR family interview and the fact that the data collection forms were based on patients' self-reports.

Conflict of Interests

The authors report no conflicts of interest.

Source of Institutional and Financial Support

No institutional or financial support was received.

Author Contributions

Concept (ÇIM,YE), Study Design (ÇIM,YE), Auditing/Consultancy (YE), Data Collection (ÇIM), Data Analysis and Interpretation (ÇIM), Literature Review (ÇIM), Manuscript Writing (ÇIM), Final Review Before Submission (ÇIM,YE).

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