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Protocol

The effect of ınformation about the operating room environment with virtual reality glasses on the anxiety level and vital findings of the patients: a randomized controlled study protocol

Serpil Cagliyan Payas[1]*, Nuray Şahin Orak[2]

[1]Department of Nursing, Institute of Health Sciences, Marmara University, İstanbul, Turkey
[2]Department of Nursing, Faculty of Health, Sciences, Nisantasi University, İstanbul, Turkey

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***Correspondence:**
Dr. Serpil Cagliyan Payas,
E-mail: serpil.caglayan@emu.edu.tr

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ABSTRACT

Background: This article summarizes the study protocol currently used to evaluate the effect of informing about the operating room environment with virtual reality (VR) glasses on patients' anxiety level and vital signs.
Methods: This study was designed as a non-drug clinical, randomized controlled trial. Eligible patients will be randomly assigned to one of two groups. The population of the study will consist of 80 patients who will undergo planned abdominal surgery in the operating room unit of a state hospital affiliated to the TRNC ministry of health. Before surgery, the first group (n=40) will be informed through VR glasses, while the second group (n=40) will receive standard care.
Conclusions: The outcome is anxiety level before surgery and the state of vital signs during surgery.
Trial registration: International standard randomized controlled trial number NCT05899790.

Keywords: Preoperative anxiety, VR, Abdominal surgery, İnformation about the operating room environment

INTRODUCTION

Abdominal surgical intervention; refers to surgical interventions on organs in the abdominal region such as stomach, bile, liver, spleen, pancreas, small intestine, large intestine.[1,2] Despite increasing technological developments, scientific evidence and recommendations, major or minor complications related to abdominal surgical interventions can be seen. It is reported that more than 300 million surgical interventions are performed on average worldwide every year, and abdominal surgical interventions performed in developed countries increase by 2-5% every year.[3-5] Surgical interventions, which are widely used in the promotion of health and the treatment of diseases, are one of the most important experiences in an individual's life. While surgical interventions, whether simple or life-threatening, are a positive event that will provide relief from the disease, it becomes an anxiety-inducing situation because the individual loses control over his body for a limited time and does not have enough knowledge about this subject.[6-9]

The most basic cause of anxiety before surgical intervention is the fear of the unknown.[10] It is known that more medical complications develop in patients with high anxiety levels during the surgical process. Although the factors that trigger anxiety vary greatly among individuals, the effects of generalized or long-term anxiety states are generally similar. These factors may cause effects such as sinus tachycardia, hypertension, cardiac arrhythmias, post-surgical pain, increased anesthesia and analgesia requirements, wound healing process and delay in the discharge process.[11,12]

The complex and unusual environments of operating rooms and the situation of receiving anesthesia cause

anxiety and fear in the patient.[13] In particular, the time spent in the pre-operative waiting area was defined as the period in which most patients imagine the potential dangers of the surgery and envision their pain in the sharpest way, and it was reported as a trigger for the level of anxiety.[14,11] In a study examining the opinions of patients about the operating room environment, it was determined that only 20.1% of the patients who received training on the surgical process received information about the operating room environment, and it was determined that the information about the operating room environment was insufficient in the preoperative education of the surgical patient.[13] However, the nurse's responsibilities include informing the patient and providing psychological support to the patient, as well as the physical care of the patient.[15] The first of eight items specified for the pre-surgical period within the scope of ERAS Guidelines; In the preoperative period, patients may have fears and concerns about the surgical intervention and it is necessary to inform the patients verbally and in writing during this period.[16]

In this direction; interventions to reduce the anxiety level should be planned by creating a safe and comfortable environment for the patient.[17] Considering the limited time that the surgical team has to spend with their patients before the surgical intervention, the patient should be informed about the operating room environment, the communication techniques used for information and other non-medical interventions should be precise and effective methods.[11,14]

Drugs used to calm individuals experiencing intense anxiety can interact with anesthetic drugs used during surgery, and suddenly discontinuing these drugs can increase anxiety symptoms.[18] Since the focus on pharmacological interventions in the current management of anxiety increases the complications that may develop in the patient, easy-to-use, non-invasive non-pharmacological applications are needed. For these reasons, the need for non-pharmacological methods is increasing today. Among the non-pharmacological methods for reducing anxiety, distracting interventions such as informing the patient before surgical intervention, humor, distraction, interactive toys, puzzles, card or electronic games, rhythmic breathing, listening to music, directed images, watching television or relaxation videos, VR applications.[19-23]

VR applications, one of the approaches that have been frequently emphasized in the field of health recently; It has taken its place as a viable intervention method in various fields of medicine to distract the patient by providing attractive materials that can distract the patient's attention from a stressful situation, to experience by being exposed to the stressful event, and to alleviate anxiety.

H1: There is a statistically significant difference between the anxiety level mean scores of the patients who were informed about the operating room environment with the VR application and the patients who received standard care.

H2: There is a statistically significant difference between the surgical intervention vital signs of the patients who were informed about the operating room environment with the VR application and the patients who received standard care.

Aim

In this study, it is aimed to evaluate whether the use of SG application as one of the cognitive-behavioral methods in care practices to reduce anxiety levels can be integrated and to evaluate the effects of healthcare professionals in terms of efficient use of time and workforce. It is thought that there may be studies that can provide evidence.

METHODS

Determination of the sample size

In this study, the effect size for the anxiety scores of the experimental and control group participants was determined as 0.63. Accordingly, the sample size required for 95% (1-β=0.95) power at the d=0.63 and α=0.05 level was calculated as 71 people. Considering that there may be losses during the study process, it was planned to include 40 people for each group and 80 people in total.

Ethical considerations

This study will be conducted in accordance with the declaration of Helsinki (WMA general assembly, Fortaleza, Brazil, October 2013) and the principles of medical research activities involving human subjects, and written informed consent will be obtained from all participants throughout the study. This study was approved by the TRNC Ministry of Health, Dr. Burhan Nalbantoğlu State hospital ethics committee [Protocol number: 64/21 Date: 17.12.2021]. In addition, permissions were obtained from the authors who conducted the validity and reliability study of the scale to be used for the use of the scale and the permissions of the Institution.

Population and randomization

This study protocol describes as a non-drug clinical, randomized controlled trial.

This trial will be carried out with patients who will undergo planned abdominal surgery in the operating room unit of a state hospital affiliated to the TRNC ministry of health. The study was registered at Clinicaltrials.gov in May 2023 (NCT05899790). The study was planned as two groups. Patients who

underwent abdominal surgery will be screened for inclusion and exclusion criteria, and those who qualify will be invited to the study. After obtaining the informed written consent of the participants who agreed to participate in the study, the randomization list created from the computer-based random numbers table will be used with the block randomization method to assign an equal number of people to all two groups. The program "Graphpad" will be used for the randomization process. Participants will be given a sequence number according to the order of inclusion in the study as well as will be assigned to one of two groups according to the numbers in the randomization list.

Inclusion criteria

A 18 years and older, no visual, auditory or mental problems, conscious, with place-person-time orientation, ability to understand and respond to research instructions, communicating in Turkish, having planned abdominal surgery, volunteer to participate in the study patients who give consent will be included in the study.

Exclusion criteria

It was determined as the patients who regularly use any chemical and herbal medicine for their anxiety problem, have a diagnosis of hypertension, have a diagnosis of cardiac arrhythmia, have facial injuries that prevent comfortable use of VR equipment, and receive premedication were excluded.

Blinding

Due to the nature of this study, blinding will not be possible.

Interventions

After randomization, the 1st group will be informed about the operating room environment with VR application in the clinic and in the preoperative waiting area before the abdominal surgery, while the 2nd group will receive standard care in the clinic and in the preoperative waiting area. In order to prevent the groups from being affected by each other during the study process, the patients will be taken to the area where the intervention will be performed one by one. If this cannot be achieved, it will be ensured that the patient in the control group is in a suitable environment outside the room during the intervention.

All groups will fill in the individual characteristics form and surgical anxiety scale one day before the surgical intervention, simultaneously anxiety will be measured with GSR, and then the patient's vital signs (body temperature, pulse, respiration and blood pressure) will be evaluated and recorded. Afterwards, VR will be applied to the 1st group, and no attempt will be made to the 2nd group. Half an hour after the VR application, surgical anxiety scale will be applied to all groups again, anxiety will be evaluated simultaneously by GSR, and then their vital signs will be evaluated and recorded.

When the patients are taken to the operating room waiting area on the day of surgery, the surgical anxiety scale will be applied to all groups, and their anxiety will be measured simultaneously with the GSR and their vital signs will be evaluated and recorded. Patients in the 1st group will be shown the informative video about the operating room environment via VR, and no intervention will be made in the 2nd group. Just before the patients are sent to the operating room for surgical intervention, a surgical anxiety scale will be applied to all groups, their anxiety will be measured simultaneously with the GSR, and their vital signs will be evaluated and recorded.

During the surgery, the vital signs of the patients in all groups will be recorded every 15 minutes.

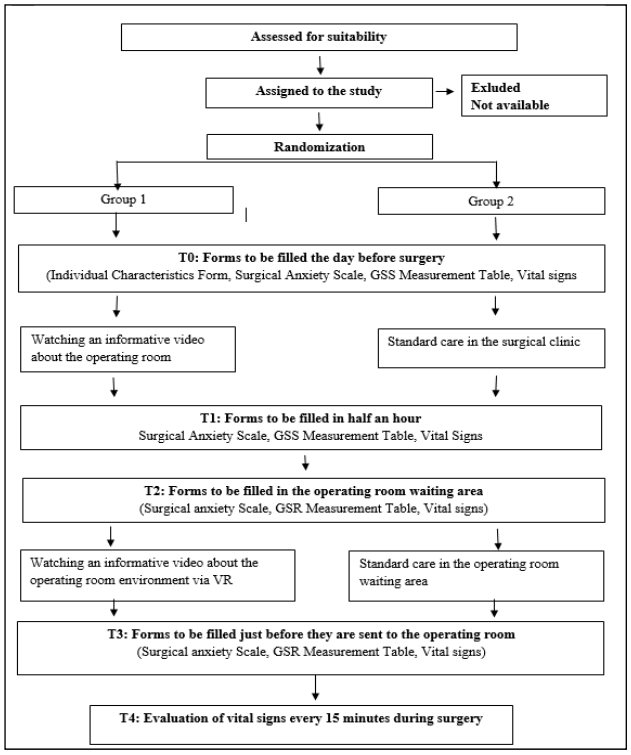

Figure 1: Data collection procedure.

Outcomes

Pre-operative anxiety

It has been reported that patients with a high level of anxiety before surgery experience high anxiety after surgery, have high pain levels, and experience more frequent problems such as nausea and vomiting.[14,24] Among adults, the prevalence of pre-surgical anxiety in association with a surgical procedure or anesthesia ranges from 60-80%. Therefore, anxiety management has an important place in the pre-surgical period.[14,25,26]

The preoperative anxiety of the patients will be evaluated with the surgical anxiety scale. The validity and reliability study of the scale developed by Burton et al in 2018 for the Turkish population was conducted by Göl in 2021.[27,28] The 17-item scale is in five-point Likert type, scored as "never-0", "very little-1", "Moderate-2", "very-3" and "extremely-4". The scale is easy to apply, and the patient is marked by considering how much each item reflects his or her own state in the pre-surgical period. The scale has three sub-dimensions: health-related anxiety (Articles 7, 8, 9, 10, 12 and 13), healing-related anxiety (Articles 2, 14, 16 and 17) and procedural anxiety (Articles 1, 3, 4 and 5). Surgical Anxiety Scale total score is obtained by summing the sub-dimension scores and the scores of three items not included in these sub-dimensions. The lowest score that can be obtained from the scale is 0, and the highest score is 68, and the higher the score, the higher the level of surgical anxiety. The scale has no cut-off point. The higher the score, the higher the surgical anxiety level is.

Galvanic skin sensor (GSS) measurement

GSS; means galvanic skin response. It is a commonly used approach to measure the electrical conductivity of the skin. In the national and international literature, studies evaluating anxiety level with different anxiety scales before surgical intervention are frequently used.[26,29-31] However, studies in which anxiety is evaluated with GSR, one of the non-invasive methods are rare.[11]

In our study, besides the use of the "surgical anxiety scale" to evaluate the anxiety level before surgery, the anxiety level will also be evaluated with the GSR.

Vital signs

Anxiety is an uncomfortable situation that causes behavioral and physiological changes in the patient. This emotional response, which occurs in the pre-surgical period, results in the activation of the sympathetic and parasympathetic nervous systems as well as the endocrine system. Stimulation of these pathways leads to general constriction of blood vessels, an increase in heart rate, blood pressure and sweating.[30]

Vital signs, 1 day before surgery in the clinic; before the VR application and 30 minutes after the VR application, on the day of the operation, when the patient arrives in the operating room waiting area; It will be evaluated before VR and just before being sent to surgery.

Vital signs evaluated during surgery will be recorded every 15 minutes.

Data collection procedure

This is an RCT study conducted in the surgical ward and operating room waiting area before abdominal surgery. To assign an equal number of subjects to all two groups, patients who underwent abdominal surgery, met eligibility criteria, and gave written informed consent, will be assigned to the group using block randomization.

Individual characteristics form, which contains patient demographic and clinical information, surgical anxiety scale, GSS measurements, and vital signs will be collected in the one day before the surgery (T0). A follow-up measurement (T1) will be made 30 minutes after the VR application. Measurements will be repeated when the patient is brought to the operating room waiting area (T2) and just before being sent to the operating room (T2). Then vital signs will be recorded every 15 minutes throughout the operation period (T4).

Statistical analysis

SPSS 26 statistical analysis program shall be used for evaluating the study data. The acquired data shall be tested at 95% confidence interval, $p<0,05$ level of significance. Number, percentage distributon and standard deviation for the definitive data analysis, chi square test for experiment and control groups' basic particulars similarity, Shapiro-Wilk for normality analysis of dependent variables, Student t test or Annova for the comparison of pre-test and final test scores of experiment control groups, the comparisons of variables giving normal distribution among the groups as per the normal distributon in the comparison of experiment control groups' pre-test and final test scores, Mann Whitney U test or Kruskal Wallis test for the variables of non-normal distribution shall be used.

DISCUSSION

Approximately 80% of patients who are scheduled for surgery experience varying degrees of anxiety due to pain, fear of complications during or after surgery, or fear of death.[11,32] Current management of anxiety primarily focuses on pharmacological interventions such as prescribing anxiolytic or sedative drugs.[11,31,33] However, these drugs are known to cause serious side effects such as respiratory depression, drug dependence, nausea and vomiting, drowsiness, decrease in blood pressure and heart rate, anaphylaxis, organ failure, delayed awakening from anesthesia, delayed discharge from the postoperative care unit, and rarely death.[11,25,33-35] For this reason, easy-to-use, non-invasive applications are needed to reduce the anxiety levels of patients in the preoperative period.[36]

For the purpose of distraction, which is among the cognitive behavioral techniques; Comedy, distraction, interactive toys, puzzles, card or electronic games, rhythmic breathing, listening to music, directed images, watching television or relaxation videos, VR applications are among the techniques that are frequently preferred today.[21,22,23] The use of VR in clinical settings has increased in recent years due to its non-invasiveness and

painlessness, reusability, low cost compared to hypnosis and drug therapy, and increased accessibility.[31,37-42] Given the limited time the surgical team has to spend with their patients prior to surgical intervention, patient information regarding the operating room environment, communication techniques used for information, and other non-medical interventions should be precise and effective methods.

In the international literature, there are studies showing the effectiveness of SG, which is one of the cheap, simple and applicable methods in various patient populations to relieve/reduce anxiety before surgical intervention.[11,31,35,42-46] However, no study has been found in the international and national literature investigating the effect of informing the operating room environment via SG before the abdominal surgery on the patients' anxiety level before the surgery and their vital signs during the surgery. In addition, although studies evaluating anxiety level with different anxiety scales before surgical intervention are common in the national and international literature, studies evaluating anxiety with GSR, one of the non-invasive methods, are rare.[11] In our study, besides the use of the "surgical anxiety scale" to evaluate the anxiety level before surgery, the anxiety level will also be evaluated with the GSR.

In the light of this information, studies that can provide evidence are needed to evaluate whether the use of SG application as one of the cognitive-behavioral methods in care practices to reduce the anxiety levels of patients before abdominal surgery can be integrated.

CONCLUSION

This article summarizes the protocol of a randomized controlled trial conducted to demonstrate the effectiveness of Information about the operating room environment with VR glasses on the anxiety level and vital findings of the patients.

There are studies showing the effectiveness of SG. However, this is the first study in which the effect of informing about the operating room environment through SG on the patients' anxiety level before surgery and their vital signs during surgery.

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