REPUBLIC OF TURKIYE

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EVALUATION OF THE EFFECTIVENESS OF VIRTUAL REALITY APPLICATION DURING CESAREAN DELIVERY UNDER SPINAL ANESTHESIA

STUDY PROTOCOL

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Type and Setting of the Research

This study was designed as a randomized controlled trial to evaluate the effectiveness of virtual reality intervention during cesarean delivery under spinal anesthesia in pregnant women.

The study was conducted between November 2024 and June 2025 in the cesarean delivery unit of the Department of Obstetrics and Gynecology at a university hospital. Cesarean delivery plans are made one week in advance. Three days prior to delivery, pregnant women are called to the outpatient clinic for non-stress testing (NST), monitoring of vital signs, ultrasonography, laboratory tests, and preoperative instructions (including fasting 6–8 hours before surgery, antibiotic prophylaxis, removal of jewelry, hairpins, lenses, artificial nails, nail polish, etc., and a 48-hour postpartum hospital stay). Hospital admission is carried out between 07:00 and 08:00 on the day of delivery. Standard procedures, such as monitoring vital signs, NST, establishing intravenous access, anesthetic assessment and counseling, and obtaining written informed consent, are performed for admitted patients. Postpartum care is provided for 24 hours for vaginal deliveries and 48 hours for cesarean sections. This hospital was chosen for the study due to its high birth volume, status as one of the most preferred public hospitals in Ankara, its diverse patient population with varying socioeconomic and cultural backgrounds, and the researcher's affiliation with the institution.

Population and Sample of the Research

The population of the study consisted of pregnant women who applied to the antenatal outpatient clinic of the Department of Obstetrics and Gynecology of the relevant hospital and were scheduled for cesarean delivery. The sample was calculated based on Tuvanç's (2024) study (State-Trait Anxiety Inventory: Intervention Group $\bar{X}$±SD: 59.78±6.61 and Control Group $\bar{X}$±SD: 56.11±6.61). The sample size was calculated using the G*Power 3.1.9.7 software. Based on power analysis with α (Type I error) = 0.05 and 80.7% power, a minimum of 52 pregnant women were required—26 in the intervention group and 26 in the control group. Considering a potential dropout rate during the study, the sample size was increased by 10%, and the study was completed with a total of 60 participants. To reduce selection bias and control variables potentially affecting outcomes, 162 pregnant women were assessed using an inclusion criteria form. Of these, 102 were excluded due to multiparity (n=82), illiteracy in Turkish (n=5), or unwillingness to participate (n=15). The remaining 60 eligible participants were randomly assigned to the intervention (n=30) and control (n=30) groups using simple randomization. Participants were numbered in order of cesarean scheduling and randomized via https://randomizer.org/randomize. Groups were coded as A and B, with letters randomly assigned via draw: A representing the intervention group and B the control group. To minimize bias, the groups were coded as “A” and “B” in the dataset for statistical blinding.

In order to account for possible dropouts during the study, the sample size was increased by 10%, and the study was completed with a total of 60 pregnant women. To reduce selection bias and control variables that may affect outcome measures, 162 pregnant women were assessed using an eligibility criteria form.

Of these, 102 did not meet the inclusion criteria (Multiparity (n=82), illiteracy in Turkish (n=5), lack of voluntary consent (n=15)). The remaining 60 eligible participants were randomly assigned to the intervention and control groups using simple random sampling (Intervention Group n=30, Control Group n=30).

For the random assignment, participants were numbered based on the order they arrived for cesarean delivery and assigned using the website https://randomizer.org/randomize. To represent the intervention and control groups, the letters A and B were used. The group associated with each letter was randomly determined by draw; letter A represented the intervention group, and letter B represented the control group.

To minimize bias, statistical blinding was applied by recording the groups in the database under the codes 'A' and 'B'.

Inclusion Criteria

• Aged 19 years or older,
• Literate in Turkish,
• At least a primary school graduate,
• Between the 37th and 42nd weeks of gestation, primiparous with a single fetus,
• Scheduled to receive spinal anesthesia,
• Voluntarily agreed to participate in the study.

Exclusion Criteria

• Multiparous women,
• Women with multiple pregnancies,
• Diagnosed psychiatric disorders (e.g., anxiety disorders, bipolar disorder, schizophrenia),
• Hearing, visual, or communication impairments,
• Women who did not voluntarily agree to participate were excluded from the study.

Withdrawal Criteria

• Incomplete data collection forms,
• Voluntary withdrawal from the study at any stage,
• Administration of general anesthesia/sedation during the cesarean procedure,
• For the intervention group only: failure to fully attend the VR headset training, non-compliance with the prescribed usage duration of the VR headset, or presence of side

effects related to VR use (e.g., dizziness, headache, sweating, nausea, vomiting, or eye fatigue).

Dependent and Independent Variables of the Study

Dependent Variables of the Study

The dependent variables of the study include the use of a virtual reality headset, the Spielberger State-Trait Anxiety Inventory, the Visual Analogue Scale for Pain, and the Maternal Satisfaction with Cesarean Birth Scale.

Independent Variables of the Study

The independent variables of the study include sociodemographic characteristics, individual habits and obstetric features, characteristics of labor monitoring (preoperative vital signs, intraoperative vital signs, maternal anxiety expressions, neonatal Apgar score, side effects associated with VR headset use), and maternal vital signs in the postpartum period.

Data Collection Tools

The study utilized seven data collection tools: Eligibility Criteria Form, Individual Information Form (IIF), Pregnant Monitoring Form - Intervention Group (PMF-IG), Pregnant Monitoring Form - Control Group (PMF-CG), Spielberger State-Trait Anxiety Inventory (STAI), and the Maternal Satisfaction with Cesarean Birth Scale.

Eligibility Criteria Form

This form, prepared based on the literature, includes ten questions assessing age, literacy in Turkish, educational background, gestational week, primiparity, presence of a single fetus, diagnosed psychiatric condition, sensory or communication impairments, and planned type of anesthesia. Each question is answered with 'Yes' or 'No'. Participants who answered 'Yes' to questions 1, 2, 3, 4, 5, 6, 9, and 10, and 'No' to questions 7 and 8 were included in the study.

Individual Information Form

Prepared based on literature review, the Individual Information Form (IIF) consists of two sections with a total of 11 items aimed at identifying the demographic and obstetric characteristics of pregnant women. This form was filled out by the participants.

The first section includes five questions regarding age, educational background, employment status, engagement in regular physical activity (at least 150 minutes of moderate activity per week, WHO, 2024), and smoking habits.

The second section consists of six items assessing obstetric characteristics such as gestational week, whether the pregnancy was planned, history of abortion, history of curettage, number of antenatal follow-ups, and sources of information regarding cesarean delivery.

Pregnant Monitoring Form – Intervention Group

The Pregnant Monitoring Form for the Intervention Group (PMF-IG) consists of three sections and was completed by the researcher based on observations and hemodynamic measurements.

The first section records preoperative vital signs (heart rate, blood pressure, respiratory rate, and oxygen saturation) between 6–12 hours before the cesarean procedure.

The second section tracks intraoperative vital signs, pain level using the Visual Analogue Scale, side effects related to VR headset use, and the newborn's Apgar score.

The third section includes postpartum vital signs observed between 8–12 hours after delivery.

Pregnant Monitoring Form – Control Group

The Pregnant Monitoring Form for the Control Group (PMF-CG) also consists of three sections and was completed by the researcher based on observations and hemodynamic measurements.

The first section monitors vital signs (heart rate, blood pressure, respiratory rate, and oxygen saturation) in the preoperative period between 6–12 hours before the procedure.

The second section includes intraoperative monitoring of maternal vital signs, pain level using the Visual Analogue Scale, and the newborn's Apgar score.

The third section documents the postpartum vital signs recorded between 8–12 hours following delivery.

Visual Analogue Scale for Pain

The Visual Analogue Scale (VAS) was first developed in 1921 by Hayes and Patterson and is widely used to measure pain intensity. In addition to pain severity, it provides information on how negatively the patient feels due to the pain.

The VAS consists of a 10-cm line, either horizontal or vertical, with 'no pain' at one end and 'unbearable pain' at the other. Patients are asked to mark the point that best represents their level of pain.

The score is then measured numerically, where a score of '0' indicates no pain and '10' indicates the most severe pain. The average score typically ranges between 5 and 6. A higher score reflects a greater intensity of perceived pain.

In this study, the Visual Analogue Scale was included in the Pregnant Monitoring Form.

Spielberger Trait Anxiety Inventory

The Spielberger Trait Anxiety Inventory (STAI-T) was developed by Spielberger and colleagues in 1970. The scale was adapted into Turkish and validated by Öner and Le Compte in 1985.

This inventory is used to assess how individuals generally feel and includes 20 items. It is rated on a 4-point Likert scale: 1 (almost never), 2 (sometimes), 3 (often), and 4 (almost always).

There are seven reverse-scored items in the trait anxiety scale: items 21, 26, 27, 30, 33, 36, and 39. The reverse-scored items are coded as 4, 3, 2, and 1 instead of their original 1 to 4 ratings.

Separate answer keys are created for direct and reverse-scored items. The total score is calculated by subtracting the sum of reverse scores from the sum of direct scores, and then adding a fixed constant value of 35.

The total score ranges between 20 and 80. The average score typically falls between 36 and 41. Higher scores indicate higher levels of anxiety. The Cronbach's alpha for the trait anxiety scale in this study was found to be 0.80.

Spielberger State Anxiety Inventory

The Spielberger State Anxiety Inventory (STAI-S) was developed by Spielberger and colleagues in 1970 and adapted into Turkish by Öner and Le Compte in 1985.

It consists of 20 items used to evaluate the participant's current state of anxiety. The items are rated on a 4-point Likert scale: 1 (not at all), 2 (somewhat), 3 (moderately so), and 4 (very much so).

There are ten reverse-scored items: items 1, 2, 5, 8, 10, 11, 15, 16, 19, and 20. These items are reverse-coded in scoring.

Separate answer keys are prepared for direct and reverse-scored items. The state anxiety score is calculated by subtracting the reverse score total from the direct score total and adding a constant of 50.

The total score ranges from 20 to 80, with typical scores falling between 36 and 41. Higher scores indicate greater anxiety levels. The Cronbach's alpha value for this scale in the study ranged between 0.80 and 0.87.

Maternal Satisfaction with Cesarean Birth Scale

The Maternal Satisfaction with Cesarean Birth Scale (MSCBS) was developed by Güngör and Beji (2009) to evaluate maternal experiences during cesarean birth and in the early postpartum period.

The scale consists of 42 items and 10 subdimensions: perception of the healthcare team (items 1–5), preparation for cesarean (items 6–7), relaxation (items 8–10), participation in decisions and information (items 11–18), meeting the baby (items 19–21), postpartum care (items 22–27), hospital room (items 28–30), hospital facilities (items 31–33), respect for privacy (items 34–37), and fulfillment of expectations (items 38–42).

It is a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Twelve items (8, 9, 10, 19, 20, 21, 22, 34, 35, 37, 40, 41) are reverse-scored.

After reverse scoring, total scale and subdimension scores are calculated by summing the item scores. The total score ranges between 42 and 210, with higher scores indicating greater maternal satisfaction.

The cut-off score for high satisfaction was set at 146.5 ($\geq$146.5 = high satisfaction, $<$146.5 = low satisfaction). The Cronbach's alpha value for this scale was reported as 0.87.

Preparation of Research Materials

Virtual Reality Headset Training Brochure

A training brochure was prepared to inform pregnant women in the intervention group about the virtual reality application during the preoperative period. The brochure included detailed explanations about the effects, usage areas, and potential side effects of the VR headset.

Implementation of the Study

The study was conducted in three stages. In the first stage, pregnant women who met the inclusion criteria and volunteered to participate were randomly assigned to intervention and control groups.

In the second stage, the intervention group received a virtual reality application during cesarean delivery, while the control group received only routine hospital procedures.

In the third stage, the levels of pain, anxiety, and maternal satisfaction experienced during the cesarean section were evaluated between 8–12 hours postpartum.

Stage One: As part of the study, women who were scheduled for cesarean delivery were informed about the study during routine tests conducted three days before the operation. These included a non-stress test (NST), vital signs monitoring, ultrasonography, laboratory examinations, and preoperative preparations.

Volunteering participants completed the 'Eligibility Criteria Form.' Those who met the inclusion criteria were randomly assigned to the intervention and control groups using simple random sampling through the website https://randomizer.org/randomize based on their order of clinic admission.

Participants assigned to the groups were visited 6–12 hours before cesarean delivery in their hospital rooms. They completed the 'Individual Information Form,' the 'Spielberger Trait Anxiety Inventory,' and the 'Spielberger State Anxiety Inventory.'

In both groups, researchers conducted hemodynamic measurements and recorded preoperative vital signs in the first section of the Pregnant Monitoring Form.

In addition, pregnant women in the intervention group received training about the VR headset application and underwent a 5-minute trial to assess potential side effects. After training, they were given the 'VR Headset Training Brochure.'

Stage Two: At this stage, the identities of the pregnant women in both groups were verified, and they were admitted to the operating room.

During this process, spinal anesthesia was administered by an anesthesiologist using a 22-gauge spinal needle at the L3-L4 or L4-L5 interspace, with 10 mg of bupivacaine and 0.05 mg of morphine diluted in 3 ml injected into the subarachnoid space.

In the intraoperative period, the virtual reality intervention was applied twice to the pregnant women in the intervention group.

The first VR application was performed for approximately 5 minutes during the assessment of the effectiveness of spinal anesthesia and was removed to allow the patient to rest. The resting period, during which spinal anesthesia takes full effect, averaged about 10 minutes.

The second VR application was initiated at the time of surgical incision and continued until the head, extremity, or breech of the fetus was visible, approximately lasting 10 minutes. The VR application was terminated upon birth of the newborn.

To assess anxiety levels during the cesarean, the Spielberger State Anxiety Inventory was administered during the spinal anesthesia rest phase.

In addition, maternal vital signs, pain levels, side effects related to VR use, and the newborn's Apgar score were recorded by the researcher on the Pregnant Monitoring Form.

The VR headset used in this study was the Meta Quest 2 All-in-One model by Oculus. It is a head-mounted display, with each lens offering a resolution of 1832x1920 pixels and a 360° field of view.

The pregnant women in the intervention group viewed a licensed video titled 'Breathe – Relax and Meditate' via the Meta Horizon application on the VR headset.

To maintain hygiene and comfort, a disposable VR headset cover and single-use surgical cap were used around the forehead and ears during application. The headset was disinfected before each use.

According to the literature, the maximum duration of VR application should not exceed 20 minutes due to potential side effects such as dizziness, headache, nausea, vomiting, and eye fatigue. Therefore, the VR sessions in this study were limited to 15 minutes to minimize adverse effects.

In the control group, no additional interventions were performed other than the routine cesarean delivery procedures.

To assess anxiety levels during the cesarean, the Spielberger State Anxiety Inventory was administered during the spinal anesthesia rest phase.

During the cesarean delivery, maternal vital signs, pain scores, and the newborn's Apgar scores were recorded by the researcher on the Pregnant Monitoring Form.

Stage Three: In this final stage, participants from both groups were visited in the ward within the first 8–12 hours postpartum. The 'Maternal Satisfaction with Cesarean Birth Scale' was completed by the participants.

Additionally, maternal vital signs were measured and recorded in the Pregnant Monitoring Form.

Ethical Considerations of the Research

Before commencing the study, ethical approval was obtained from the Ethics Committee of Ankara Yıldırım Beyazıt University Faculty of Health Sciences and written permission was secured from the hospital where the study was conducted.

Participants were informed about the study's purpose and content, and written informed consent was obtained.

They were assured that all personal data would remain confidential and that they could withdraw from the study at any time without any consequences.

Permissions for the use of the data collection tools were obtained from the respective scale authors via email.