

Official Title:

[Effect of Virtual Reality–Assisted Nursing Intervention on Pain and Anxiety During Intrauterine Device Insertion: A Randomized Controlled Trial]

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Study Sponsor:

[Mersin University]

Principal Investigator:

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Study Description**Brief Summary:**

The aim of this study was to evaluate the effect of a virtual reality-assisted nursing intervention on participants' pain, anxiety, physiological parameters and comfort levels during IUD insertion. In this context, the study hypothesises that the virtual reality application will reduce pain and anxiety during the procedure, support physiological stability, and enhance participants' comfort levels was designed as a randomised controlled trial.

The study's hypotheses:

Individuals receiving the virtual reality-supported nursing intervention, compared to the control group;

- experience a lower level of pain during the procedure.
- experience lower levels of anxiety during the procedure.
- exhibit lower levels of stress response in physiological parameters (heart rate, blood pressure and respiratory rate).
- experience higher levels of comfort during the procedure.

Condition or illness: Pain, anxiety, physiological parameters and comfort levels of individuals during IUD insertion

Intervention: Virtual reality-assisted nursing intervention

Stage: Women who have decided to have an IUD fitted

Detailed Description

Study Design

Study Type: Interventional (Clinical Study)

Actual Number of Participants: 70 participants

Assignment: Random

Intervention Model: Parallel Assignment

Intervention Model Description: Prospective, parallel, two-arm, randomized controlled clinical trial, single-blind

Blinding: Single (participant)

Methods: The sample size for the study was calculated to be a minimum of 64 following a power analysis conducted using the G*Power 3.1.9.4 programme, based on a 5% significance level ($\alpha=0.05$), 95% power and an effect size of 0.40. Taking potential data losses into account, the study was planned to include a total of 70 participants (experimental = 35, control = 35).

Randomisation and Groups

In this study, given the nature of the intervention, it was anticipated that conducting the experimental and control groups on the same day could lead to information transfer between participants via communication (contamination) and behaviour changes related to the intervention (Hawthorne effect). Furthermore, administering the virtual reality application to some participants whilst not administering it to others within the same clinical setting could create a perception of unequal treatment among individuals, which could influence the study results.

Therefore, to minimise the risk of contamination and maintain the integrity of the clinical trial, participants were assigned to groups on a day-by-day basis. Participants who enrolled on specific days of the week were included in the experimental group, whilst those who enrolled on other days were included in the control group.

The similarity of baseline characteristics between the groups will be assessed statistically.

Intervention

Experimental Group: VR Group

Participants in the experimental group were subjected to a virtual reality-assisted nursing intervention during the IUD insertion procedure. As part of this, participants were shown a 3D video lasting approximately 6 minutes, featuring nature-themed scenes (water, forest, sky) and accompanied by soothing music, via virtual reality goggles.

This intervention was designed as a non-pharmacological nursing intervention aimed at diverting the individual's attention away from the procedure and reducing pain and anxiety levels.

Control Group: Not VR Group

Participants in the control group will not receive any additional interventions beyond the routine care provided in the clinic during the IUD insertion procedure.

Data Collection Tools

Data were collected in three phases: pre-procedure, during the procedure, and post-procedure.

Pre-procedure: A 7-item Information Form comprising demographic and descriptive characteristics; the General Comfort Scale, developed by Kolcaba in 1992, with Turkish validity and reliability studies conducted by Kuşuoğlu & Karabacak in 2008, consisting of three sub-dimensions (refreshment, relaxation, superiority) and 48 items; General Comfort Scale and a 4-item Visual Analogue Scale assessing anxiety, fear/apprehension, irritability and satisfaction regarding the IUD procedure, and by assessing blood pressure, pulse and respiratory rate.

During the procedure, pain levels immediately following the insertion of the speculum, tenaculum and IUD will be assessed using the Visual Analogue Scale, and the pulse will be checked at each stage.

After the procedure, blood pressure, pulse, and respiratory rate were assessed, and a 5-item Visual Analogue Scale covering pain, tension, fear/anxiety, irritability, and satisfaction regarding the IUD insertion will be administered, along with the General Comfort Scale.

Materials to be Used in the Study:

- a. Virtual Reality Headset: Samsung GearVR2 SM-R321NZWATUR Virtual Reality Headset
- b. Video Prepared for the Virtual Reality Environment: As part of the study, the experimental group will be shown a virtual reality video titled 'Virtual Nature 360°- 5K Nature Meditation for Daydream, Oculus, Gear VR', which features nature scenes accompanied by calming music.

Data Collection

Data will be collected by trained researchers using the face-to-face interview method. The data collection process will take an average of 15–20 minutes.

Participants will be informed about the research and an "Informed Consent Form" will be administered. The researcher will know who is in the experimental and control groups, but participants will not know which group they belong to. Participants will be blinded. Due to the nature of the research, the researcher cannot be blinded. When the research is complete, the data will be transferred to a computer environment by an independent researcher who does not know groups A and B, and the data will be analyzed by a statistician and the findings reported.

The study data were collected between February 2024 and December 2025. Ethical approval was obtained from the SANKO University Clinical Research Ethics Committee with decision number (date:21.12.2023) 2023-24. Informed consent was obtained from the participants.

Statistical Analysis

Data analysis will be conducted using the SPSS programme.

Primary Goal: To reduce pain and anxiety related to IUD insertion, and to increase satisfaction and comfort

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Actual Study Start Date: April 30, 2026

Actual Primary Completion Date: June 30, 2026

Actual Study Completion Date: October 30, 2026

Eligibility Criteria

Eligible Ages for Participation: 18 years and older (Adult)

Eligible Genders: Female

Healthy Volunteers Accepted: Yes

Criteria

Inclusion Criteria: Who

Inclusion criteria for the study;

- Being 18 years and older
- Being sexually active
- Having decided to have an IUD inserted
- Being gynecologically suitable for an IUD
- Having no communication impediment

Exclusion criteria:

- Visual or hearing impairment
- Diagnosed psychiatric illness
- History of epilepsy
- Severe dizziness or condition that prevents VR use
- IUD contraindications detected during gynecological examination

Study Termination Criteria

1. Failure of the participant to complete all stages of the study for any reason during the data collection process,

3. The participant's request to withdraw from the study.

Location: Turkey, Mersin University, Mersin, Yenişehir, Turkey, 33343

Sponsors and Collaborators:

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Keywords provided by Yasemin ATEŞEYAN, Mersin University: Virtual Reality, Intrauterine Device, Pain, Anxiety, Nursing Intervention, Randomized Controlled Trial, Women's Health, Gynecological Procedures, Non-pharmacological Intervention