

The Impact of Virtual Reality-Assisted Relaxation on Breastfeeding Self-Efficacy and Breast Milk Production in Mothers of Premature Infants: A Randomized Controlled Trial

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STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN (SAP)

1. BACKGROUND AND RATIONALE

Breast milk is essential for premature infants' health and development. However, mothers of preterm infants often experience high stress levels due to the Neonatal Intensive Care Unit (NICU) environment, which can negatively affect milk production and breastfeeding confidence. This study aims to investigate whether Virtual Reality (VR) based relaxation can increase milk volume and self-efficacy.

2. OBJECTIVES

Primary Objective: To compare the daily breast milk volume between the VR intervention group and the control group over three days.

Secondary Objective: To evaluate the effect of VR relaxation on breastfeeding self-efficacy scores.

3. STUDY DESIGN

Type: Randomized Controlled Trial (Parallel Group).

Setting: A Level II Neonatal Intensive Care Unit.

Duration: 3 consecutive days for each participant.

4. PARTICIPANT SELECTION

Inclusion: Primiparous mothers of infants born at 32-35 weeks of gestation, delivered via C-section, willing to express milk.

Exclusion: Systemic/psychiatric diseases, use of galactagogues, or visual/hearing impairments.

Sample Size: 44 participants (22 Intervention, 22 Control).

5. INTERVENTION PROTOCOL

Experimental Group: Participants use a VR headset to watch a 10-minute nature video with classical music in a quiet room. Immediately after, a trained researcher performs manual milk expression for at least 20 minutes.

Control Group: Participants sit in the same quiet room for 10 minutes without VR. Then, the same manual milk expression procedure is performed by the researcher.

Timing: All sessions occur between 12:00 and 14:00 to ensure hormonal consistency.

6. STATISTICAL ANALYSIS PLAN (SAP)

- Data will be analyzed using SPSS software.
- **Descriptive Statistics:** Mean, standard deviation, median, and percentages will be used.
- **Normality Test:** Shapiro-Wilk or Kolmogorov-Smirnov.
- **Comparison:** Mann-Whitney U test for comparing the two independent groups.
- Friedman test for evaluating changes over the 3-day period within groups.
- Spearman's correlation to examine the relationship between variables.
- Significance Level: $p < 0.05$.

Prepared by:

Assistant Professor Suzi Özdemir, RM, PhD

Kocaeli University, Faculty of Health Sciences, Midwifery Department

suzi.ozdemir@kocaeli.edu.tr