

STUDY PROTOCOL

Official Title

**The Effect of Virtual Reality on Pain and Anxiety During Arteriovenous Fistula
Cannulation in Hemodialysis Patients: A Randomized Controlled Study**

ClinicalTrials.gov Identifier

NCT Number: Not yet assigned

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ABSTRACT

Aim: This study was conducted to determine the effect of virtual reality (VR) goggles used during arteriovenous fistula (AVF) cannulation in hemodialysis patients on pain and anxiety levels.

Material and Methods: The study was designed as a parallel-group randomized controlled experimental trial. The study was conducted with 50 patients (experimental group n=25, control group n=25) receiving treatment at a dialysis center. Patients in the experimental group were shown visual-auditory content via VR goggles during AVF needle insertion, while the control group received routine care. Data were collected using the Demographic Information Form, the Visual Analog Scale (VAS), and the State Anxiety Inventory (SAI). Data analysis involved the Mann-Whitney U, Wilcoxon, Spearman Correlation, and Simple Linear Regression tests.

Results: No significant difference was found between the groups' pre-test pain and anxiety scores ($p=1.000$). Post-intervention, the experimental group's pain ($U=96.500$; $p<0.001$; $r=0.61$) and anxiety ($U=125.000$; $p<0.001$; $r=0.52$) were found to be significantly lower than those of the control group. Regression analysis revealed that 36.4% of the change in patients' anxiety levels was directly explained by pain levels ($R^2=0.364$; $p<0.001$). Additionally, a strong positive correlation was found between pain and anxiety ($\rho=0.610$; $p<0.001$).

Conclusion: It was concluded that the virtual reality application is an effective method for reducing AVF cannulation pain and the associated situational anxiety. It is recommended that VR be used as a routine intervention for pain management in hemodialysis units.

Keywords: Hemodialysis, Virtual Reality, Pain, State Anxiety, Nursing Care.

MATERIALS AND METHODS

Inclusion and Exclusion Criteria for Participants Inclusion criteria were defined as being 18 years of age or older, receiving treatment via AVF, having no visual impairment, and giving voluntary consent.

Exclusion criteria: Patients with catheter use, communication problems, antipsychotic medication use, analgesic use in the last 12 hours, and unsuccessful (multiple) needle insertion attempts were excluded from the study.

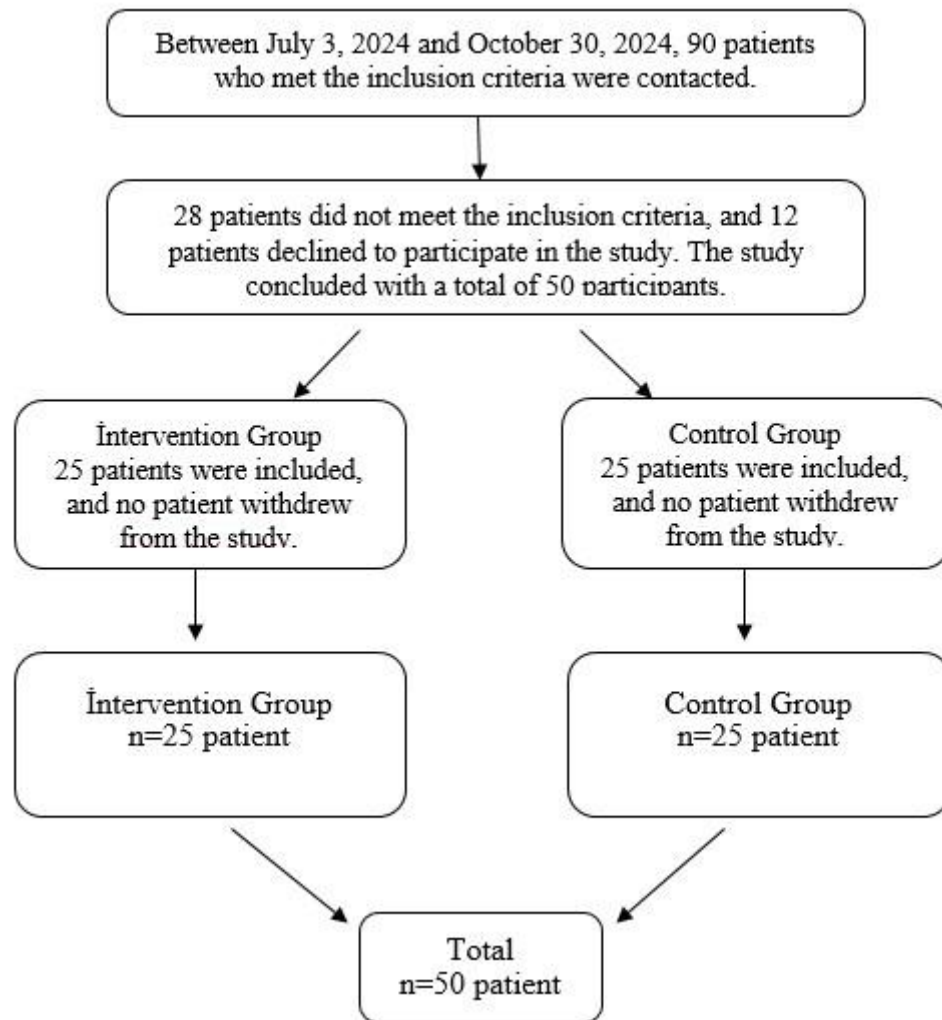


Figure 1: sample diagram

Study Implementation After determining the randomization list for the patients to be included in the study, informed consent was obtained from the patients, and the Descriptive Characteristics Form, Visual Analog Scale (VAS), and State Anxiety Inventory (SAI) were administered. Then, according to the randomization list, patients were assigned to experimental and control groups. After the groups were determined, AVF needle insertion was performed in the experimental group with virtual reality glasses. To ensure equalization of needle insertion in the study, all patients in both the experimental and control groups were cannulated with a size 16 arterial and venous needle positioned at least 5 cm away from the fistula area at a 30°–45° angle, with the diagonal edge facing upwards, by an experienced hemodialysis nurse. The needle was then secured using hypoallergenic tape. Fifteen minutes after fistula insertion, the glasses were removed, and the Visual Analog Scale (VAS) and State Anxiety Inventory (SAI) were administered for the second measurement.

Ethical Aspects of the Research

The research was conducted in accordance with the Helsinki Declaration. Permission was obtained from the Ethics Committee for Scientific Research in Health Sciences of Necmettin

Erbakan University, Republic of Turkey, for the implementation of the research (Decision Number: 2024/809, Application ID: 20172). Institutional permission was also obtained from the Private Konya Daviva Dialysis Center Directorate where the research was conducted. Before the application, the individuals to be included in the research were informed by the researcher about the purpose of the study and the application steps, and their written consent was obtained using the "Informed Consent Form" (See Appendix 1). Permission was obtained from the authors for the use of the "VAS" and the "State Anxiety Inventory" used in the research.