STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Official Title:

THE EFFECT OF VIRTUAL REALITY INTERVENTION ON PAIN LEVEL, STATE ANXIETY, AND VITAL SIGNS DURING FOOT CARE IN INDIVIDUALS WITH DIABETIC FOOT ULCERS

NCT Number:

Pending

Document Date:

January 2026

Sponsor:

Malatya Turgut Ozal University

Principal Investigator:

Yasemin Ozkul

1. BACKGROUND AND RATIONALE

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by hyperglycemia, resulting from deficient insulin secretion, reduced insulin action, or both. According to the 11th edition of the International Diabetes Federation (IDF) Diabetes Atlas (2025), approximately 589 million adults worldwide are living with diabetes, and this number is projected to reach 853 million by 2050 (IDF, 2025). In Turkey, the prevalence of diabetes has increased from 7.2% (TURDEP-I, 1997-1998) to 13.7% (TURDEP-II, 2010), placing the country among the highest-prevalence nations in the European region. As of 2024, approximately 7.5 million adults aged 20-79 in Turkey are estimated to have diabetes (IDF, 2025; American Diabetes Association Professional Practice Committee, 2024).

Diabetic foot ulcer (DFU) is one of the most serious and burdensome complications of diabetes. The lifetime risk of developing a foot ulcer in individuals with diabetes is 19-34%, and approximately 20% of these lesions may result in lower extremity amputation (Armstrong et al., 2023). A multicenter study conducted in Turkey found active DFU in 17.1% of adult patients with diabetes, underscoring the national significance of this problem (Armstrong et al., 2023).

Diabetic foot care is a complex nursing procedure that involves wound assessment, infection control, appropriate dressing application, and patient education (Armstrong et al., 2023). During this process, patients frequently experience significant procedure-related pain and anxiety, which can impair adherence to care, trigger stress-related changes in vital signs (pulse rate, respiratory rate, blood pressure), and prolong healing. Therefore, simultaneous management of pain, anxiety, and vital sign stability is considered an important component of nursing practice in diabetic foot care.

In recent years, growing interest in non-pharmacological approaches for pain and anxiety management has led to the investigation of virtual reality (VR) as a distraction-based intervention. VR immerses the individual in an interactive three-dimensional digital environment, cognitively distracting them from nociceptive stimuli. This mechanism is supported by the Gate Control Theory (Melzack & Wall, 1965), which posits that competitive sensory input can suppress pain signal transmission to the central nervous system. Evidence from pediatric and adult settings has demonstrated that VR reduces pain and anxiety during invasive procedures such as wound care, vascular access, vaccination, and post-operative recovery, and may exert stabilizing effects on heart rate, blood pressure, respiratory rate, and oxygen saturation (Zeng et al., 2019; Baidhowy et al., 2024).

Despite promising evidence in other clinical settings, studies specifically addressing VR during diabetic foot care are limited (Baidhowy et al., 2024). The present study was therefore designed to rigorously evaluate the effect of a VR intervention on pain, state anxiety, and vital signs in patients with diabetic foot ulcers undergoing wound care in a hospital setting.

2. STUDY OBJECTIVES AND HYPOTHESES

2.1 Primary Objective

To determine the effect of virtual reality (VR) application during foot care on the pain level, state anxiety, and vital signs (body temperature, oxygen saturation, pulse rate, respiratory rate, systolic and diastolic blood pressure) of individuals with diabetic foot ulcers.

2.2 Study Hypotheses

$H1_1$: Virtual reality application during foot care has an effect on pain level in individuals with diabetic foot ulcers.

$H1_2$: Virtual reality application during foot care has an effect on state anxiety in individuals with diabetic foot ulcers.

$H1_3$: Virtual reality application during foot care has an effect on vital signs in individuals with diabetic foot ulcers.

3. STUDY DESIGN

This study is a single-center, randomized controlled experimental trial with a pre-test/post-test design, conducted at Malatya Turgut Ozal University Training and Research Hospital (Orthopedics Unit and Chronic Wound Care Unit), Malatya, Turkey.

Study Period: December 9, 2024 - June 15, 2025

Study Design: Randomized Controlled Trial (RCT)

Blinding: Single-blind (outcome assessor blind to group allocation)

Allocation: Random (computer-generated block randomization list)

4. STUDY POPULATION

4.1 Target Population

Adult individuals with diabetes mellitus who were receiving diabetic foot wound care at the Orthopedics Unit and Chronic Wound Care Unit of Malatya Turgut Ozal University Training and Research Hospital, Malatya, Turkey.

4.2 Inclusion Criteria

- Age >= 18 years
- Confirmed diagnosis of Type 2 Diabetes Mellitus
- Presence of a diabetic foot ulcer classified as Grade 3 or Grade 4 according to the Wagner Classification System (Wagner, 1981)
- Ability to communicate verbally
- Able to read and write Turkish
- Willingness to participate in the study and provide written informed consent

4.3 Exclusion Criteria

- Presence of a chronic wound other than diabetic foot (e.g., arterial or venous ulcer)
- Age < 18 years
- Cognitive impairment or altered level of consciousness precluding completion of study measures
- Inability to use VR goggles (e.g., severe visual or vestibular disorder)

4.4 Sample Size

The sample size was calculated using G*Power 3.1 software. In the absence of studies specifically examining VR in diabetic foot patients, the effect size (d = 0.46) was derived from a meta-analysis by Zeng et al. (2019) on VR effects on anxiety and pain. With alpha = 0.05 and power = 0.95, the required sample was 64 participants (32 per group). Accounting for approximately 5% possible attrition, 68 participants were randomized. Analyses were performed on the 64 participants who completed the study.

5. RANDOMIZATION AND BLINDING

5.1 Randomization

Eligible participants were randomized to the intervention or control group using a computer-generated random selection method. Randomization was performed individually for each participant immediately after completion of pre-test measurements and prior to the onset of foot care. This approach minimized selection bias.

5.2 Blinding

A single-blind design was adopted. Outcome measurements (vital signs, state anxiety, pain) were performed by an independent assessor who was blinded to group allocation. Participants and the primary investigator administering the VR intervention were not blinded due to the nature of the intervention.

6. INTERVENTIONS

6.1 Intervention Group - Virtual Reality Application

Participants in the intervention group wore a VR headset (VR Shinecon G40E 3D VR goggles paired with a Samsung Galaxy A30 smartphone) throughout the duration of the diabetic foot care procedure. A curated library of relaxing, nature-themed 360 degree virtual environments was available for patients to choose from. VR content had been selected and piloted prior to the study for acceptability, absence of motion sickness, and suitability for the clinical setting.

Infection control measures: The VR headset was cleaned and disinfected before and after each use according to hospital infection control protocols. Contact surfaces were wiped with single-use 70% isopropyl alcohol disinfectant wipes and allowed to dry completely. Single-use earpad covers were applied for each participant and disposed of as medical waste after use.

6.2 Control Group - Standard Care

Participants in the control group received routine standard diabetic foot care without any additional intervention. No VR or other distraction technique was applied.

7. OUTCOME MEASURES AND DATA COLLECTION INSTRUMENTS

7.1 Primary Outcomes

Pain level: Visual Analog Scale (VAS) - a 10 cm horizontal line anchored at 0 ('no pain') and 10 ('worst imaginable pain'), developed by Price et al. (1983). Scores recorded to 0.1 cm precision.

State anxiety: State-Trait Anxiety Inventory - State subscale (STAI-I), a validated 20-item self-report scale scored 20-80, with higher scores indicating greater anxiety (Spielberger et al., 1970).

7.2 Secondary Outcomes (Vital Signs)

- Body temperature (degrees C) - non-contact infrared thermometer (Life Net Medical JA-11C)
- Oxygen saturation / SpO2 (%) - fingertip pulse oximeter (Life Net Medical PFX033)
- Pulse rate (beats/min) - pulse oximeter
- Respiratory rate (breaths/min) - direct observation and counting

- Systolic blood pressure (mmHg) - upper-arm automated sphygmomanometer (Omron M3 Comfort HEM-7155-E)
- Diastolic blood pressure (mmHg) - same device

7.3 Demographic Data

A Demographic Information Form was used to collect participant characteristics including age, sex, education level, duration of diabetes, wound grade, and analgesic medication use.

7.4 Data Collection Procedure

Data were collected at two time points using a face-to-face interview technique by the principal investigator:

Pre-test: Approximately 5 minutes before the start of foot care (after a minimum 5-minute rest period in the seated position). The Vital Signs Form, STAI-I, and VAS were administered. Participants were then randomized.

Post-test: Immediately after completion of foot care (within 0-2 minutes). The Vital Signs Form, STAI-I, and VAS were re-administered.

To ensure measurement standardization, all measurements were performed by the same researcher using the same equipment with participants in the same position. For blood pressure measurements, patients had rested for >= 5 minutes in a seated position and had abstained from caffeine for >= 1 hour and smoking for >= 15 minutes prior to measurement.

8. STATISTICAL ANALYSIS PLAN

Data analysis was performed using SPSS version 22.0. The level of statistical significance was set at alpha = 0.05 for all tests.

8.1 Normality Testing

The Shapiro-Wilk test and visual inspection of Q-Q plots were used to assess normality of continuous variables. Descriptive statistics are presented as mean +/- standard deviation (SD) for normally distributed variables and as median (IQR) for non-normally distributed variables. Categorical variables are presented as frequency (n) and percentage (%).

8.2 Between-Group Comparisons at Baseline

Independent samples t-test was used for continuous variables and chi-square test for categorical variables to verify baseline comparability of the intervention and control groups.

8.3 Within-Group Pre-Post Comparisons

Paired samples t-test was used to compare pre-test and post-test scores within each group (intervention and control) for all outcome variables.

8.4 Between-Group Comparisons of Change Scores

Independent samples t-test was used to compare the magnitude of change (post-test minus pre-test) between the intervention and control groups for each outcome variable.

8.5 Effect Size

Cohen's d was calculated to quantify the practical significance of between-group differences. Interpretation: d < 0.2 = negligible; 0.2-0.5 = small; 0.5-0.8 = medium; > 0.8 = large.

9. ETHICAL CONSIDERATIONS

The study was approved by the relevant institutional ethics committee and conducted in accordance with the Declaration of Helsinki. All participants received a full explanation of the study purpose, procedures, potential risks and benefits, and their right to withdraw at any time without consequence. Written informed consent was obtained from all participants prior to enrollment. No participant names or identifiable personal information are included in this document or in the reported dataset.

The investigators declare no conflicts of interest in relation to this study.

10. KEY REFERENCES

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