Study Protocol

Official Title: A Story-Based Digital Game to Reduce Anxiety and Improve Treatment Compliance in Hemodialysis Patients: A Randomized Controlled Trial

NCT Number: To be assigned

Ethics Committee Approval Number: E.888577

Study Period: March 2025 – April 2025

Study Protocol

Title: A Story-Based Digital Game to Reduce Anxiety and Improve Treatment Compliance in Hemodialysis Patients

Protocol Version: 1.0

Protocol Date: March 1, 2025

Principal Investigator(s): Dr. Afra Çalık, Assoc. Prof. Sıddıka Ersoy

Institution: Suleyman Demirel University, Department of Nursing

Sponsor: Suleyman Demirel University BAP Coordination Unit

1. Project and Study Dates
Project Duration (BAP-Funded): January 3, 2025 – June 17, 2025
Study Implementation Dates: March 1, 2025 – April 30, 2025

2. Ethical Approval
The study protocol was reviewed and approved by the Ethics Committee of Suleyman Demirel
Ethics Approval Number: E.888577
Ethics Approval Date: 11.15.2024

3. Background and Rationale
Hemodialysis patients often face psychological stress, low adherence, and dietary mismanagement. This study introduces a story-based digital game to educate and emotionally support patients during dialysis sessions.

4. Objectives
- To evaluate the impact of a digital game on treatment adherence
- To assess improvements in dietary knowledge
- To determine reductions in anxiety levels among participants

5. Study Design
This is a single-center, single-blinded randomized controlled trial. Participants are assigned to either the intervention (digital game) group or control (standard care) group. Sessions were separated to prevent contamination, and the statistician was blinded to group assignment.

6. Study Population
Inclusion Criteria:
- Age 18–80 years
- At least 6 months on hemodialysis
- Literate
- Consent provided

Exclusion Criteria:
- Cognitive impairment or refusal to consent

7. Intervention Description

The digital game features a fictional character beginning dialysis. Patients mentor this character through challenges, reinforcing their own knowledge on diet, fluid management, and self-care. Each session lasts 10–15 minutes.

8. Outcome Measures

Primary:
- End-Stage Renal Disease Adherence Scale
- Hemodialysis Patients' Diet Knowledge Scale
- State Anxiety Scale

Secondary:
- Game Experience Questionnaire (GAMEX)

9. Statistical Analysis

Data will be analyzed per the Statistical Analysis Plan (SAP). Non-parametric methods (Mann–Whitney U, Friedman test) and Bonferroni-corrected Wilcoxon tests will be used. SPSS v26.0 will be employed.

10. Informed Consent and Confidentiality

Informed consent will be obtained from all participants prior to enrollment. Participant confidentiality will be ensured. All data will be anonymized.

11. Monitoring and Reporting

Adverse events will be monitored throughout the study. All protocol deviations and issues will be documented and reported.