Statistical Analysis Plan

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

Statistical Analysis Plan (SAP)

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Study Protocol Version: 1.0

Study Period: March 2025 – April 2025

Project Funding Period: January 3, 2025 – June 17, 2025

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1. Overview

This Statistical Analysis Plan (SAP) outlines the methods and procedures for the analysis of data collected from a randomized controlled trial investigating the effects of a story-based digital game intervention on treatment adherence, dietary knowledge, and anxiety among hemodialysis patients.

2. Objectives and Hypotheses

Primary Objective:
- To evaluate whether a story-based digital game intervention improves treatment adherence, dietary knowledge, and reduces anxiety in patients undergoing hemodialysis.

Hypotheses:
- H1: Patients receiving the digital game intervention will show higher adherence scores.
- H2: Patients receiving the intervention will demonstrate improved dietary knowledge.
- H3: Anxiety levels will decrease more significantly in the intervention group than in the control group.

3. Study Design Summary

This study follows a single-center, single-blinded, randomized controlled design with two parallel arms: an intervention group and a control group. Patients were randomized (1:1) to either group.

4. Statistical Methods

The analysis will follow the intention-to-treat principle. Descriptive statistics will be calculated for all variables. Continuous variables will be presented as mean ± standard deviation, and categorical variables as frequencies and percentages.

Between-group comparisons of continuous variables will use the Mann–Whitney U test. Repeated measures within each group will be analyzed using the Friedman test. Post hoc analyses will be conducted using the Wilcoxon signed-rank test with Bonferroni correction where applicable. Chi-square or Fisher's exact tests will be used for categorical data.

Statistical significance will be determined at a two-sided alpha level of 0.05.

5. Variables and Measurement Tools

- Adherence: Measured using the End-Stage Renal Disease Adherence Scale.
- Dietary Knowledge: Assessed via the Hemodialysis Patients' Diet Knowledge Scale.
- Anxiety: Measured using the State Anxiety Scale.
- Game Experience: Evaluated using the GAMEX Scale in the intervention group.

6. Assumptions and Adjustments

Given the small sample size and the ordinal nature of the scales used, non-parametric tests were selected. Multiple testing adjustments will be made using Bonferroni correction. Data will be analyzed using IBM SPSS v26.0.