

Statistical Analysis Plan (SAP)

Title:

Effects of a Virtual Reality–Based Empathy Program on Empathy, Attitudes Toward Older Adults, and Empathic Behavior Among Nursing Assistants: A Cluster Randomized Controlled Trial

NCT No.: NCT07044492

Protocol Version: 4.0

Date: October 13, 2025

IRB Approval: Taipei Medical University Joint Institutional Review Board

IRB No.: N202203004

Principal Investigator: Principal Investigator (PI)

1. Analysis Population

All randomized participants with available outcome data were included in the analysis according to the intention-to-treat (ITT) principle.

2. Outcome Definition

The primary outcome was the empathy level score, and the secondary outcomes were attitudes toward older adults and empathic behavior; all outcomes were treated as continuous variables.

3. Descriptive Statistics

Baseline characteristics were summarized by group using:

- Mean and standard deviation for continuous variables
- Frequency and percentage for categorical variables

4. Primary Analysis

The primary analysis evaluated changes in empathy level, empathic behavior and attitudes toward older adults over time between groups using linear mixed-effects models (LMMs).

4.1 Model Specification

- Fixed effects: group, time, group \times time interaction
- Random effects: cluster (care unit/ward) and participant
- Covariance structure: unstructured

The primary parameter of interest was the group \times time interaction term.

5. Handling of Clustered Data

Clustering at the care unit/ward level was accounted for through random effects in the mixed-effects models.

6. Handling of Missing Data

Missing outcome data were handled using multiple imputation (MI) under the missing-at-random (MAR) assumption.

Mixed-effects models were estimated using maximum likelihood methods, allowing inclusion of participants with incomplete outcome data.

7. Sensitivity Analyses

Sensitivity analyses were conducted to assess the robustness of findings under alternative missing data assumptions.

8. Statistical Software

All analyses were performed using IBM SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA).

9. Statistical Significance

All statistical tests were two-tailed with a significance level of $\alpha = 0.05$.

10. Deviations from the Protocol

Any deviations from the pre-specified analysis plan were documented and justified prior to data analysis.