Statistical Analysis Plan (SAP)

EFFECTIVENESS OF A MULTIMODAL INTERVENTION WITH SIMULATION FOR LEARNING HOME HEALTH NURSING CARE OF PATIENTS WITH MULTIMORBIDITY AND HEART FAILURE

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Protocol identification number:	087_2024
ClinicalTrials.gov identifier:	NCT06855719 (started: 2025-03-10)

Author of the SAP:	Antonio-Jesús Marín-Paz

Current state:	- Data collection completed. Registration in database not started (2025-05-23). - SAP remains unchanged. Statistical analysis completed and analysis code forwarded to Principal Investigator (2025-06-30).
Version:	2.0 (2025-06-30)

Abbreviations

- CG: Control Group.
- CONSORT 2025: Consolidated Standards of Reporting Trials 2025.
- EG: Experimental group.
- EPQ: Educational Practices Questionnaire (student version).
- ESSAF: High Fidelity Clinical Simulation satisfaction scale in students.
- INACSL: International Nursing Association of Clinical Simulation and Learning.
- JSE-S: Jefferson Scale of Empathy, student version.
- PI: Principal Investigator.
- RCT: Randomised controlled trial.
- SAP: Statistical Analysis Plan.
- SCLS: Student Satisfaction and Self-Confidence in Learning scale.

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1. Introduction

The aging population has increased the prevalence of patients with multiple pathologies and heart failure, creating new demands for personal and family resources to optimize their quality of life. This necessitates specialized and personalized home care from nursing professionals. Therefore, it is crucial that nursing students, who will be delivering this care in the coming years, receive adequate training.

The main objective is to evaluate the effectiveness of a multimodal intervention utilizing high-fidelity simulations of home health nursing care in enhancing the theoretical and practical skills of undergraduate nursing students for the care of patients with multimorbidity and heart failure.

This statistical analysis plan will provide a comprehensive overview of the study outcomes and their intended analysis.

2. Methods

2.1. Study design

A parallel randomized controlled trial (RCT) was conducted, employing a 1:1 allocation ratio for the control group (CG) and the experimental group (EG). The study adhered to the CONSORT 2025 (Consolidated Standards of Reporting Trials) (Hopewell et al., 2025*a*, 2025*b*) and INACSL (International Nursing Association of Clinical Simulation and Learning) recommendations for its proper execution. Recruitment commenced two weeks prior to the study's start, during which nursing students enrolled in the 'Family and Community Nursing I' course at the Faculty of Nursing were identified.

Subsequently, and prior to the study's commencement, an external researcher generated a randomization list for participants in blocks of sizes 4 and 6 using concealed random sequence generation software. Participants were then randomly assigned, with half allocated to the CG and the other half to the EG, respectively.

The intervention was conducted concurrently with the subject's scheduled teaching activities. The CG engaged in traditional learning, primarily theoretical instruction, and participated in simulations during the pretest and post-test phases without individual debriefing. In contrast, the EG received an individual debriefing report that included performance feedback and an audio-visual recording of their simulation. Following the pretest, the EG also attended a group debriefing session. Subsequently, they received specialized training on providing home visit care for patients with multimorbidity and heart failure, informed by clinical protocols and current scientific evidence.

The study was implemented from March (pretest) to April (post-test) 2025. No participants were lost during this period; however, the final data collection for satisfaction was extended until May 2025. The flow of the recruitment process and the study is depicted in Fig. 1.

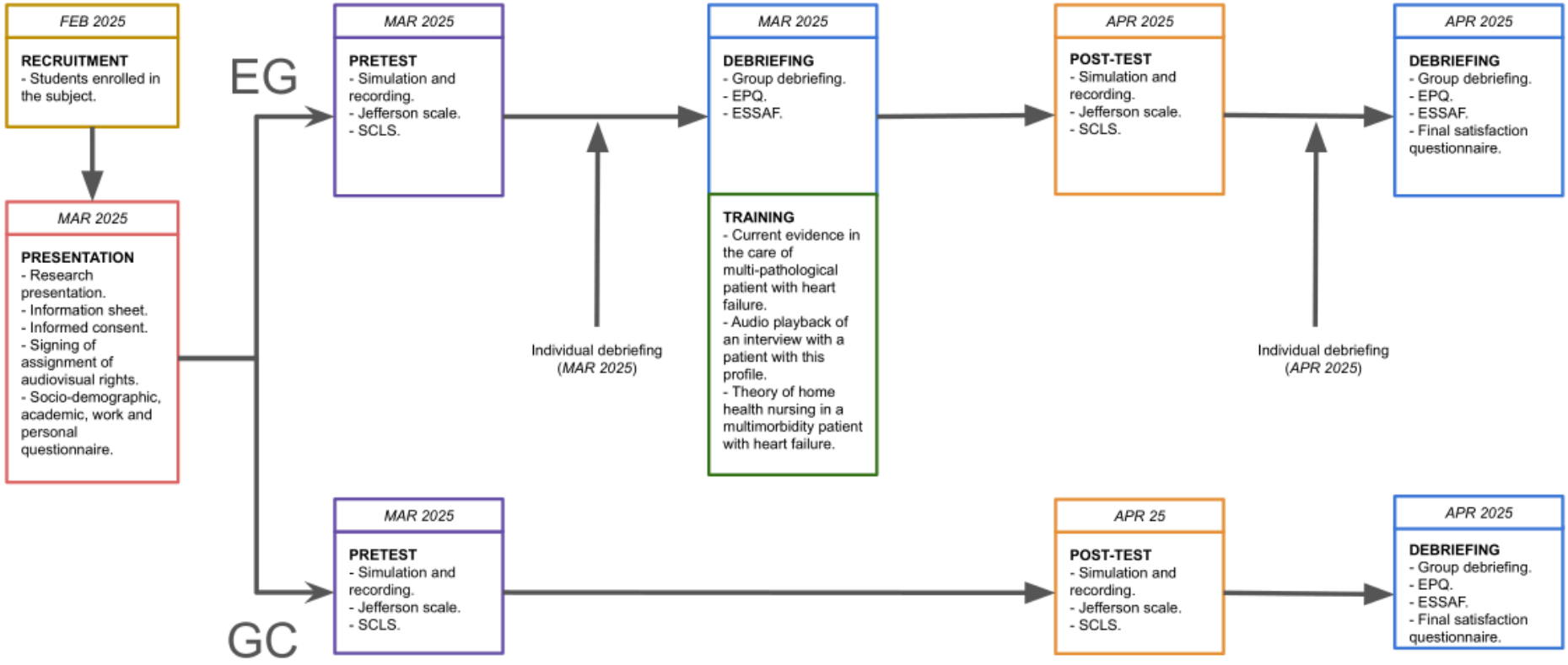

Fig. 1. Flowchart of the design of the study conducted

2.2. Sample size calculation

As all students enrolled in the subject during the recruitment period constituted the study population, a sample size calculation was not applicable.

3. Outcomes

This section outlines the outcomes explored to address the main aim of the study. The details of these analyses can be found in Section 5.

3.1. Primary outcomes

3.1.1. Learning

Data collection for both the EG and the CG spanned from enrollment to the end of the 4-week intervention period, encompassing both pretest and post-test assessments.

Learning will be assessed through nursing students' performance during the simulations. Two independent observers, experienced in simulation-based teaching, evaluated each simulation (pretest and post-test) using a validated checklist specific to each scenario. The checklist measures the following aspects: (1) assessment of patients and home environment observation (4 items), (2) nursing intervention (5 items), and (3) transferable skills related to greeting, farewell, and communication (5 items). Each item is scored dichotomously (Yes/No), and a final overall evaluation (0-10 points) is provided. The inter-observer agreement will be determined by Cohen's kappa.

3.1.2. Empathy

Data collection for both the EG and the CG was conducted from enrollment through the conclusion of the 4-week intervention, encompassing both pretest and post-test assessments.

Empathy toward patients presenting with multimorbidity and heart failure is essential for providing professional care. Students' empathy levels were assessed using the Spanish version of the *Jefferson Scale of Empathy, student version* (JSE-S), which demonstrated a Cronbach's alpha coefficient of 0.90 (Díez et al., 2022). The JSE-S is a 20-item instrument specifically developed to measure empathy in health professions education and patient care, suitable for administration to both students and practitioners. Items are rated on a 7-point Likert-type scale (1 = Strongly Disagree, 7 = Strongly Agree). Half of the items are positively worded and directly scored, while the other half are negatively worded and reverse-scored. The total score ranges from 20 to 140, with higher scores indicating greater empathy.

3.2. Secondary outcomes

3.2.1. Self-confidence in learning

Data collection for the EG and the CG occurred from student enrollment through the conclusion of the 5-week intervention period, encompassing both pretest and post-test assessments.

Student satisfaction and self-confidence in learning were measured immediately after each simulation using the *Student Satisfaction and Self-Confidence in Learning Scale* (SCLS). This scale utilizes a five-point Likert-type format, with responses ranging from 'strongly disagree' to 'strongly agree'. Possible scores on the SCLS range from 13 to 65 points. Its Spanish version was validated with a Cronbach's alpha coefficient of 0.90 (Farres-Tarafa et al., 2021).

3.2.2. Quality of simulations

Data collection for the EG and the CG spanned from student enrollment to the conclusion of the 5-week intervention period. For the EG, both pre-test and post-test assessments were conducted, while the CG underwent only post-test evaluation.

Following the individual and group debriefings, the *Educational Practices Questionnaire (student version)* (EPQ) was administered. This questionnaire comprises 16 items, each rated on two separate 5-point scales to assess both quality and importance. The Spanish version of the EPQ was validated with Cronbach's alpha coefficients of 0.86 and 0.91 for its respective scales (Román-Cereto et al., 2022).

3.2.3. Satisfaction on simulations

Data collection for the EG and the CG spanned from student enrollment to the conclusion of the 5-week intervention period. For the EG, both pre-test and post-test assessments were conducted, while the CG underwent only post-test evaluation.

Following the individual and group debriefings, student satisfaction with the high-fidelity clinical simulation was assessed using the *High Fidelity Clinical Simulation Satisfaction Scale in Students* (ESSAF). This scale comprises 33 statements, each rated on a 5-point Likert-type scale ranging from 1 (strongly disagree) to 5 (strongly agree). The 33 items are categorized into eight factors or dimensions reflecting student perception of the simulation experience: 'Usefulness,' 'Characteristics of cases and applications,' 'Communication,' 'Perceived performance,' 'Increased self-confidence,' 'Relationship between theory and practice,' 'Facilities and equipment,' and 'Positive aspects.' The ESSAF was validated with a Cronbach's alpha coefficient of 0.857 (Alconero-Camarero et al., 2019).

4. Study population

The study population comprised the entire cohort of students, who were randomly allocated in a 1:1 ratio to either the EG or the CG. A two-month follow-up period was established, and no participant attrition occurred during the intervention.

Baseline data included socio-demographic, academic, and occupational information, specifically: gender, age, number of cohabitants, housing type, academic level, and occupation during their studies. Additionally, personal experiences related to family care were gathered using dichotomous response items. Given the nature of the participants and the relatively modest population size, no intervention subgroups were formed.

5. Data analysis

An external researcher, expert in univariate and bivariate statistics, including effect size determination, will perform the database recording and statistical analysis. This investigator will be blinded to participant group allocation and will have full access to all collected data.

To meet the study objectives, the researcher will use the latest version of the statistical analysis plan (SAP), as published in the protocol registered on *ClinicalTrials.gov* (NCT06855719), to derive the necessary statistical results for the outcomes. SPSS statistical software will be utilized for this purpose. The analysis is scheduled to be conducted between May and June 2025.

5.1. Primary outcomes

Univariate statistics will be performed for the learning and empathy outcomes. Continuous variables will be reported using summary measures (means or medians) and measures of dispersion (standard deviation or interquartile range). Categorical variables will be presented as frequencies and percentages.

For bivariate analyses, the chi-square test or Fisher’s exact test will be employed for qualitative variables. The Shapiro-Wilk test will be used to assess the normality of quantitative variables. Intergroup analysis will then be conducted using Student's t-test for independent samples if distributions are normal, and the Mann-Whitney U-test for non-normal distributions. For intra-group analysis (pre-test vs. post-test), Student's t-test for paired samples will be applied for normal distributions, with the Wilcoxon signed-rank test used when this premise is not met. For relationships between quantitative variables, Pearson's correlation will be utilized for normal distributions, while Spearman's rank correlation will be used for non-normal distributions.

The level of significance or type I error to be used is 0.05. Likewise, the effect size will be determined in case of significant differences using Cohen's d, Rosenthal's r, Cramer's V, among others.

5.2. Secondary outcomes

Self-confidence in learning, the quality of simulations, and satisfaction with simulations will be analyzed using the same statistical methods applied to the primary outcomes.

6. Missing data

No missing data occurred because outcome data were collected using online forms, where all items, except for two open-ended questions, were mandatory. Furthermore, the research team ensured that all participants submitted their responses on time throughout the study, thereby preventing attrition.

7. References

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Farrés-Tarafa, M., Bande, D., Roldán-Merino, J., Hurtado-Pardos, B., Biurrun-Garrido, A., Molina-Raya, L., Raurell-Torredà, M., Casas, I., & Lorenzo-Seva, U. (2021). Reliability and validity study of the Spanish adaptation of the "Student Satisfaction and Self-Confidence in Learning Scale" (SCLS). *PLoS ONE*, *16*(7), e0255188. https://doi.org/10.1371/journal.pone.0255188

Hopewell, S., Chan, A.-W., Collins, G. S., Hróbjartsson, A., Moher, D., Schulz, K. F., Tunn, R., Aggarwal, R., Berkwits, M., Berlin, J. A., Bhandari, N., Butcher, N. J., Campbell, M. K., Chidebe, R. C. W., Elbourne, D., Farmer, A., Fergusson, D. A., Golub, R. M., Goodman, S. N., … Boutron, I. (2025a). CONSORT 2025 statement: Updated guideline for reporting randomised trials. *BMJ*, *2025,* e081123. https://doi.org/10.1136/bmj-2024-081123

Hopewell, S., Chan, A.-W., Collins, G. S., Hróbjartsson, A., Moher, D., Schulz, K. F., Tunn, R., Aggarwal, R., Berkwits, M., Berlin, J. A., Bhandari, N., Butcher, N. J., Campbell, M. K., Chidebe, R. C. W., Elbourne, D., Farmer, A., Fergusson, D. A., Golub, R. M., Goodman, S. N., … Boutron, I. (2025b). CONSORT 2025 explanation and elaboration: Updated guideline for reporting randomised trials. *BMJ*, *2025*, e081124. https://doi.org/10.1136/bmj-2024-081124

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Analytic Code

EFFECTIVENESS OF A MULTIMODAL INTERVENTION WITH SIMULATION FOR LEARNING HOME HEALTH NURSING CARE OF PATIENTS WITH MULTIMORBIDITY AND HEART FAILURE

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Protocol identification number:	087_2024
ClinicalTrials.gov identifier:	NCT06855719 (started: 2025-03-10)
Current state:	Statistical analysis completed and analysis code forwarded to Principal Investigator (2025-06-30).
Statistical analysis software	SPSS® v.24

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3.1. General data

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4.1. General data

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5.1. General data

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