STUDY PROTOCOL WITH STATISTICAL ANALYSIS PLAN

Managing Aggression! Evaluating the Effectiveness of Model-Based Standardized Patient Simulation: A Parallel Mixed-Methods Randomized Controlled Trial

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Managıng Aggressıon! Evaluatıng The Effectıveness Of Model-Based Standardızed Patıent Sımulatıon: A Parallel Mıxed-Methods Randomızed Controlled Trıal

Background

Aggression is a behavior that intentionally aims to cause physical harm to people or property (Tordjman, 2022). Encountering aggression and violent behavior from patients is a common and challenging situation for both nurses and nursing students (Hallett et al., 2021). Managing aggression is a difficult but equally important issue for healthcare professionals (Ayhan and Hiçdurmaz, 2020). Inappropriate approaches to aggression can jeopardize quality patient care and the safety of healthcare professionals, other patients, and patients' relatives (Ayhan and Hiçdurmaz, 2020). The current literature shows that nursing students may be exposed to various forms of aggression, including verbal and physical aggression, during clinical practice (Hallett et al., 2021). When confronted with aggression, nursing students may feel anxiety, anger, and inadequacy, which may lead some to consider leaving the profession (Hallett et al., 2021). Therefore, it has become critically important for nursing students to acquire the skills to recognize early signs of aggression, assess potential risks, ensure environmental safety, and manage aggression using appropriate communication techniques for their academic and clinical development (Bulut and Yıldırım, 2024). However, the literature indicates that there are limited studies describing effective and structured teaching approaches aimed at improving aggression management skills (Casey, 2024). Therefore, aggression management skills need to be supported in a practical and safe educational environment.

Various teaching strategies are used to prepare nursing students for communicating with patients who have mental health issues. Methods such as peer education and blended learning help students bridge the gap between theoretical knowledge and practical application (Casey, 2024). However, simulation-based education provides a learning environment where students can experience realistic situations without real clinical risk and observe their emotional and behavioral responses. The use of simulation is defined as an effective method for preparing nursing students for real-life situations (Casey, 2024). Recent studies have shown that model-based simulation applications can develop not only students' cognitive knowledge level but also clinical skills such as emotional regulation, increased performance, and team coordination (Gent and Kainth, 2022). However, no simulation study specifically designed for aggression management and based on a specific model has been found in the literature yet.

Rationale

Simulation-based education provides a safe and structured learning environment where nursing students can experience realistic clinical situations without putting patients or themselves at risk. Previous studies have shown that simulation improves students' self-confidence, communication skills, and clinical decision-making abilities. However, evidence regarding structured, model-based simulation interventions specifically designed for aggression management is limited.

This study aims to evaluate the effectiveness of integrated standardized patient simulation with the “De-Escalation Model in Simple Form” on nursing students' perceptions of aggression and perceived learning outcomes.

Research Hypotheses:

H0a: The De-Escalation Model based standardized patient simulation has no statistically significant effect on nursing students' perceptions of aggression.

H1a: The De-Escalation Model based standardized patient simulation has a statistically significant effect on nursing students' perceptions of aggression.

H0b: The De-Escalation Model based standardized patient simulation has no statistically significant effect on nursing students' perceived learning levels.

H1b: The De-Escalation Model based standardized patient simulation has a statistically significant effect on nursing students' perceived learning levels.

Study design

The study will conduct a convergent parallel mixed-methods design. Quantitative data will be collected using a pre-test–post-test randomized controlled trial with an intervention group and a control group. Qualitative data will be collected concurrently using a phenomenological approach to explore participants’ experiences of the standardized patient simulation. Quantitative and qualitative findings will be analyzed separately and integrated during the interpretation phase.

Methods

The study will be conducted in a nursing simulation laboratory within the health sciences faculty of a university.

The study population will consist of fourth-year nursing students enrolled in the Mental Health and Psychiatric Nursing course during the 2025-2026 academic year. A total of 56 students will be included in the study.

Participants will be randomly assigned to either the intervention group or the control group using a simple randomization method, ensuring an equal number of participants in each group. Each group is planned to include 28 participants. Inclusion Criteria are as follows: (i) being 18 years of age or older, (ii) having taken and successfully passed the Mental Health and Psychiatric Nursing course, (iii) agreeing to participate in the study. Exclusion Criteria are as follows: (i) refusing to participate in the study

The primary outcome measure of the study, perception of aggression, will be measured using the Perception of Aggression Scale. A high mean score on the functional subscale indicates that aggression is perceived as functional/acceptable, while a high mean score on the dysfunctional subscale indicates that aggression is perceived as dysfunctional/unacceptable.

The secondary outcome measure of the study, impact of aggression, will be measured using the Impact of Patient Aggression on Carers Scale. A high score on the scale indicates that individuals are highly affected by aggression.

The tertiary outcome measure of the study, perceived learning, will be measured using the Perceived Learning Scale. An increase in the scale score indicates an increase in the level of perceived learning. All three outcome measures will be assessed at baseline and after the intervention in both the intervention and control group.

In the final stage, qualitative data will be collected from participants in the intervention group to examine their learning experiences and perceptions regarding the simulation and intervention process.

A standardized patient will be used for the simulation intervention. Prior to participation, the standardized patient will be trained on the simulation scenario, expected behaviors, and procedures to ensure consistency between simulation sessions. Written informed consent will be obtained from the standardized patient before the study begins.

Data collection will be conducted in three consecutive phases: (1) Information and pre-test, (2) simulation intervention, and (3) post-test and qualitative data collection.

In the first phase, eligible participants will be informed about the study procedures, objectives, and their rights as participants, and written informed consent will be obtained. Prior to the intervention, baseline assessments of the outcome measures, including participants' perceptions of aggression and perceived learning levels, will be conducted.

In the second stage, only participants in the intervention group will receive training in "The De-Escalation Model in Simple Form" and then participate in an aggression management simulation with a standardized patient. The simulation will be conducted in small groups using a structured and standardized scenario. During the simulation, nursing students are expected to assess environmental safety, recognize early warning signs of aggression, apply the steps of The De-Escalation Model in Simple Form (setting limits, clarifying the situation, and problem-solving), and use therapeutic communication techniques to manage patient agitation. The simulation focuses on non-physical de-escalation strategies and emphasizes patient and staff safety. Each simulation session will begin with a briefing and conclude with a debriefing session facilitated by the research team.

In the final stage, qualitative data will be collected from participants in the intervention group to examine their learning experiences and perceptions of the simulation and intervention process. Subsequently, final test assessments will be administered to both the intervention and control group using the same outcome measures.

Statistical analysis

IBM SPSS Statistics 27 software will be used for the statistical calculations and analyses of the quantitative data in the study. When evaluating the study data, frequencies (number, percentage) will be used for categorical variables, and descriptive statistics (mean, standard deviation, median, minimum, maximum) will be used for numerical variables. The normality assumptions

of numerical variables will be examined using the Kolmogorov Smirnov normality test. Depending on the normality distribution, parametric (Independent Samples T Test, etc.) or non-parametric (Mann Whitney U, etc.) statistical methods will be used. Statistical significance in the analyses will be interpreted at the $p<0.05$ level. In the qualitative part of this mixed-methods research, the written responses given by students to the questions asked during the debriefing phase will be examined using the content analysis method from qualitative data analysis methods. In this analysis, the written responses given to the questions asked to students during the simulation's analysis phase will be coded. The data will be organized by analyzing it and placing it into relevant categories. The reporting phase, which is the final step of the content analysis method, will be completed by presenting the content analysis steps and findings.

Ethical considerations

Participation in this study will be voluntary. All participants will be informed about the study's objectives, procedures, and their rights as participants, and written informed consent will be obtained prior to data collection. Simulation sessions may be video recorded, with the participants' consent, solely for educational and evaluation purposes. All recordings will be stored securely, accessible only to the research team, and permanently deleted after the study is completed. Confidentiality will be ensured through the use of coded data collection forms and secure, password-protected digital storage systems. No personally identifiable information will be included in the data sets, and study data will be used solely for research purposes and will not be shared with third parties. Upon completion of the study, participants in the control group will also be offered the same training and simulation intervention.

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Flow diagram