Structural Equation Modeling and Monte Carlo Simulation in Clinical and Nursing Research: Insights Into Sample Size, Opportunities, and Challenges

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INTRODUCTION

Structural Equation Modeling (SEM) is widely adopted in behavioral, economic, and sociological sciences, and sample size calculations in this regard typically involve Monte Carlo simulation. SEM simultaneously integrates measurement and structural components, enabling both the evaluation of construct validity and the testing of specific hypotheses. Its application is particularly relevant when analyzing self-report data or complex theoretical frameworks, which require testing hypotheses as the primary aim, involving more than one dependent variable in the same model. Clinicians are often unfamiliar with these methods, and studies involving SEM tend to employ convenience sampling without a proper sample size calculation. A critical discussion regarding opportunities and challenges in this regard could facilitate the adoption of best practices when implementing SEM, including appropriate sample size calculations.

OBJECTIVES

To highlight the potential and challenges of adopting SEM in clinical research and nursing science and to discuss the contribution of Monte Carlo simulation for sample size planning in such contexts by using a real-case application as the context of the critical discourse.

METHODS

A real-case application is presented from a randomized controlled trial (RCT) involving Health Easy, a digital ecosystem designed to enhance engagement and health literacy among adolescents with congenital heart disease. The ecosystem integrates medical term simplification (SIMPLE), a patient-centered health search engine (FACILE), and a balanced learning interface (ULearn). The pilot study informed the primary endpoint (self-care behavioral score improvement of 10% after 3 months, on a scale of 0–100, which is Cohen's d = 0.67). While classical power-based sample size calculation was applied to the primary outcome, Monte Carlo simulation was used to evaluate the statistical power to test the hypothesized structural paths underpinning the Health Easy model. These included the mediating role of health literacy in the relationship between the intervention (Health Easy) and improvements in patient engagement, where health literacy is hypothesized to mediate and moderate the effects of the digital ecosystem on self-care behaviors and empowerment.

RESULTS

Monte Carlo simulation enabled simulation-based validation of the hypothesized structural paths within the Health Easy conceptual framework, particularly those involving latent variables and indirect effects. The simulation assessed the power and estimation precision for each path, including mediating effects of health literacy and moderated pathways influencing patient engagement and self-care behaviors, by generating multiple synthetic datasets (1000 replications) under specified model parameters. The simulation output supported the stability of parameter estimates and standard errors across replications, reinforcing the robustness of the SEM design.

A traditional power analysis was conducted to detect a 10-point mean difference in behavioral scores between two independent groups (Cohen's d = 0.67, α = 0.05, power = 0.90), indicating that a total sample of 96 participants (48 per group) would be sufficient for this specific comparison. However, when this same sample size was evaluated within

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the Monte Carlo simulation framework, it yielded an empirical power of only 0.49 to detect the hypothesized small-to-moderate indirect and moderated effects typical of SEM (Cohen's d ≈ 0.3). To achieve adequate power (≥0.80) for testing the full model, a substantially larger sample, approximately 344 participants, was required. These findings demonstrate that when the objective is to test a conceptual model rather than a simple group difference, traditional power analysis may be misleading. Simulation-based approaches, such as Monte Carlo methods, are therefore essential for planning the appropriate sample size in SEM-driven clinical research.

CONCLUSIONS

SEM and Monte Carlo simulation represent valuable yet underutilized tools in clinical research. Their application allows for the rigorous evaluation of complex intervention models, particularly when outcomes are mediated by constructs such as health literacy and patient engagement. Unlike traditional power analysis, these methods accommodate the analytical complexity of real-world frameworks and offer more accurate guidance for study design. Integrating SEM and simulation-based approaches into clinical trial methodology may enhance the interpretability, precision, and validity of intervention research. To support broader adoption, the development of a collaborative research network focused on advancing and disseminating these methods is encouraged.

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