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# Clinical Skills Development and Competency Assessment Needs among Nursing Assistant Students: A Design and Development Study

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**ABSTRACT**

**Purpose of the study:** This study aimed to develop and validate a competency-based clinical skills development model for nursing assistant students and evaluate its effectiveness in improving clinical performance, procedural competence, and self-efficacy.

**Methodology:** A Design and Development Research (DDR) approach with a sequential exploratory mixed-methods design was employed. Phase 1 involved qualitative needs assessment with 24 students and 6 clinical instructors to identify competency gaps. A competency-based learning model integrating structured simulation, standardized rubrics, DOPS-based formative feedback, and OSCE assessment was subsequently constructed and validated by seven experts (S-CVI = 0.92). Effectiveness was evaluated using a quasi-experimental pre-test–post-test control group design with 64. Outcomes included OSCE performance, DOPS ratings, and clinical self-efficacy. Data were analyzed using ANCOVA and effect size calculations.

**Main Findings:** The intervention group demonstrated significantly higher post-test OSCE scores (82.6 ± 5.9 vs. 69.4 ± 6.7; $p < 0.001$; $d = 1.95$), improved DOPS ratings (4.3 ± 0.4 vs. 3.5 ± 0.5; $p < 0.001$), and increased self-efficacy (81.1 ± 7.5 vs. 64.3 ± 8.1; $p < 0.001$; $d = 2.09$) compared to controls. Skill retention at four weeks remained significantly higher in the intervention group ($p < 0.001$).

**Novelty/Originality of this study:** Findings support structured operationalization of competency-based education in assistant-level nursing training and provide an empirically grounded framework for curriculum reform.



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## 1. INTRODUCTION

The global health workforce continues to face critical shortages, particularly in long-term care, geriatric services, and community-based health systems. Nursing assistants constitute a substantial proportion of the frontline caregiving workforce and are directly involved in essential clinical procedures, patient monitoring, hygiene care, mobility support, and early detection of clinical deterioration [1]- [3]. Across European health

systems, including Eastern Europe, demographic ageing and the rising prevalence of chronic conditions have intensified the demand for clinically competent mid-level care providers [4], [5]. However, despite their centrality in service delivery, structured clinical skills development and standardized competency assessment frameworks for nursing assistant students remain inconsistently implemented across educational institutions [6]-[8]. This discrepancy raises concerns regarding preparedness for safe practice, patient outcomes, and workforce sustainability.

Clinical skills development in nursing education has progressively shifted from knowledge-based instruction toward competency-based education (CBE), emphasizing observable performance, measurable outcomes, and workplace readiness [7]-[10]. Nevertheless, most competency frameworks and validated assessment instruments have been developed primarily for registered nurses rather than nursing assistants, whose scope of practice, training duration, and clinical responsibilities differ significantly [11]-[13]. Existing literature tends to focus either on isolated skill acquisition or on general nursing competency, without integrating practical learning models with structured, context-specific assessment systems tailored to nursing assistant students [14]-[16]. Consequently, there is limited empirical evidence guiding how clinical skills training should be systematically designed, implemented, and evaluated for this specific educational level.

Within Central and Eastern European contexts, variations in curriculum design, clinical placement supervision, and assessment standards further exacerbate this gap [17]-[19]. At institutional levels, including universities offering nursing assistant pathways such as Trakia University in Stara Zagora, practical learning often relies on traditional apprenticeship-style supervision, checklist-based evaluation, and subjective instructor judgment [20]. While such approaches provide experiential exposure, they frequently lack validated competency indicators, structured feedback mechanisms, and longitudinal performance tracking [21]-[23]. The absence of a systematically developed and empirically validated clinical skills model tailored to nursing assistant students represents a critical educational and regulatory gap, particularly as European health systems increasingly emphasize accountability, patient safety, and evidence-based workforce preparation.

Furthermore, contemporary clinical education research underscores that effective skills acquisition requires more than repetition [24]; it demands structured scaffolding, simulation-based rehearsal, deliberate practice, and performance-based assessment tools such as OSCE, Mini-CEX, or Direct Observation of Procedural Skills (DOPS) [25], [26]. Yet, few development studies have explicitly investigated how these evidence-informed strategies can be adapted and validated for nursing assistant education in university-based settings [27]. While competency-based frameworks are widely advocated, there remains insufficient design and-development research that integrates needs assessment, model construction, expert validation, and empirical testing within a coherent educational intervention for nursing assistant students [28], [29].

Addressing this gap is urgent for several reasons. First, inadequate clinical competency among nursing assistants has been associated with increased risk of adverse events, delayed recognition of patient deterioration, and variability in care quality [30]. Second, inconsistent assessment practices undermine fairness, reliability, and student confidence in their clinical preparation [31]. Third, without a validated and contextually grounded learning model, educational institutions may struggle to align training outcomes with evolving healthcare demands [8]. Therefore, developing a structured, competency-based clinical skills model grounded in empirical needs assessment and rigorously validatedrepresents not only an educational innovation but also a strategic investment in patient safety and workforce resilience [32].

The novelty of the present study lies in its systematic application of a design and development research approach to (1) explore clinical skills development and competency assessment needs among nursing assistant students, (2) construct a competency-based practical learning model tailored to institutional and contextual realities, and (3) validate the model through expert review and empirical testing. By integrating qualitative exploration, framework design, and evaluative validation within a single coherent study, this research moves beyond descriptive competency mapping toward actionable educational transformation. In doing so, it contributes a contextually responsive and empirically grounded model that can inform curriculum reform, assessment standardization, and future cross-national comparative research in nursing assistant education.

Ultimately, strengthening clinical skills development and competency assessment systems for nursing assistant students is not merely an academic exercise it is a necessary response to systemic healthcare pressures and evolving standards of safe practice. Through the development and validation of a structured learning model, this study seeks to provide evidence-based guidance for enhancing practical training quality, improving competency measurement reliability, and supporting the preparation of clinically competent nursing assistants capable of meeting contemporary healthcare demands.

## 2. RESEARCH METHOD

### 2.1 Study Design

This study employed a Design and Development Research (DDR) approach within an educational design research framework to systematically develop and validate a competency-based clinical skills learning model for nursing assistant students. The design integrated sequential phases of needs assessment, model construction, validation, pilot implementation, and effectiveness evaluation [33]-[35]. A mixed-methods sequential exploratory design was embedded within the DDR framework to ensure conceptual robustness and empirical rigor [36], [37]. Qualitative data informed the development of the competency framework, which was subsequently validated and quantitatively tested for effectiveness [38].

The study was conducted at Trakia University, Stara Zagora, between October 2024 and June 2025. Participation was voluntary, confidentiality was ensured through coded identifiers, and students were informed that participation would not influence academic grading. Control group participants were granted access to the developed model after study completion to ensure educational equity.

### 2.2 Research Phases

The following describes the stages of Design and Development Research systematically and transparently.

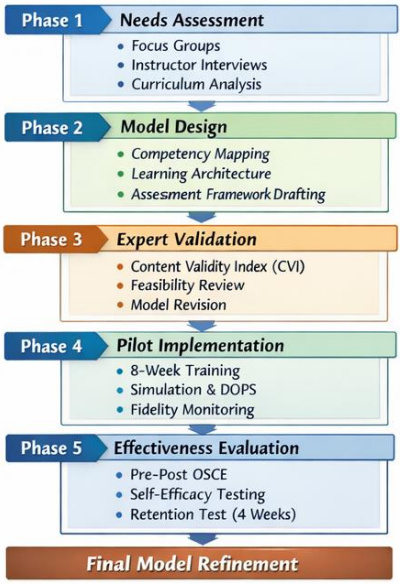


Figure 1. Sequential Phases of the Design and Development Research (DDR) Model

The research consisted of five integrated phases, presented in Table 1.

Table 1. Overview of the Design and Development Research Phases

| Phase | Objective | Participants | Data Collection | Output |
|---|---|---|---|---|
| Phase 1: Needs Assessment | Identify clinical skill gaps and assessment limitations | 24 nursing assistant students; 6 clinical instructors | Focus group discussions; semi-structured interviews; curriculum review | Competency gap mapping |
| Phase 2: Model Design | Construct competency-based clinical skills framework | Research team + 5 educational experts | Thematic synthesis; framework alignment with CBE principles | Draft learning model |
| Phase 3: Expert Validation | Establish content validity and feasibility | 7 expert panelists (nursing education, clinical supervision) | Content Validity Index (CVI); structured evaluation form | Validated model (CVI ≥0.80) |
| Phase 4: Pilot Implementation | Test feasibility and instructional clarity | 32 nursing assistant students | Simulation-based sessions; structured observation | Refined model |
| Phase 5: Effectiveness Evaluation | Assess impact on clinical competency | 64 students (intervention n=32; control n=32) | OSCE scores; self-efficacy scale; DOPS ratings | Effectiveness evidence |

The study was conducted in five sequential phases, each targeting a specific objective in the development of a competency-based clinical skills model. Phase 1 assessed students' clinical skill gaps and current assessment limitations. Phase 2 focused on designing a draft learning model based on identified needs and Competency-Based Education principles. Phase 3 involved expert validation to ensure content accuracy and feasibility. Phase 4 piloted the model to test its clarity and practical implementation, while Phase 5 evaluated its effectiveness on students' clinical competency using OSCE, self-efficacy, and DOPS measures. Collectively, these phases ensured a systematic, evidence-based, and validated approach to model development.

### 2.2 Participants and sampling

Participants were recruited using purposive sampling for qualitative phases and quasi-experimental allocation for the quantitative phase [39], [40]. Inclusion criteria included enrollment in the second year of the nursing assistant program and completion of foundational theoretical courses. For the effectiveness phase, a non-equivalent control group pre-test–post-test design was applied. Two intact student cohorts were assigned as intervention and control groups to avoid contamination bias. A priori power analysis (G*Power 3.1, $\alpha = 0.05$, power = 0.80, effect size d = 0.65) indicated a minimum sample of 60 participants; 64 students were included to account for potential attrition.

### 2.3 Development of the Clinical Skills Learning Model

The following describes the conceptual structure of the competency-based learning model that was developed.

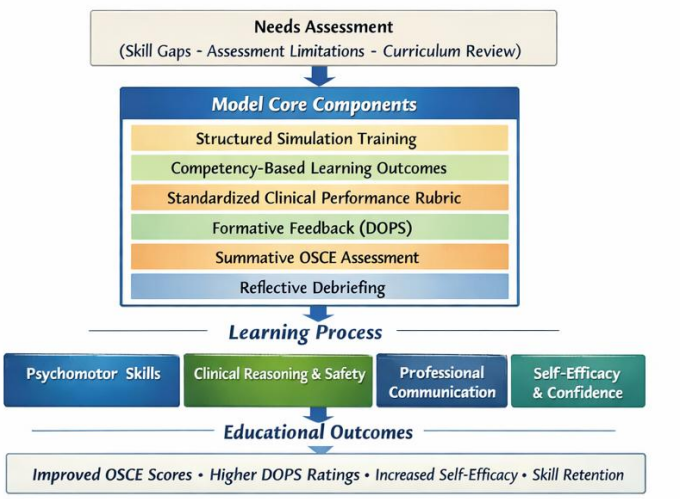


Figure 2. Conceptual framework of the competency-based clinical skills development model

The model was constructed based on findings from Phase 1 and aligned with competency-based education principles. The framework integrated three core domains:

1. Clinical procedural skills
2. Clinical reasoning and patient safety awareness
3. Professional communication and teamwork

The instructional architecture combined simulation-based training, structured clinical supervision, deliberate practice, and performance-based assessment.

Table 2. Core components of the developed learning model

| Component | Description | Educational Rationale |
|---|---|---|
| Structured Simulation Modules | High-fidelity and low-fidelity simulation sessions for wound care, vital signs monitoring, mobility assistance | Experiential learning and deliberate practice |
| Competency Rubric | Behavioral indicators across knowledge, psychomotor, and affective domains | Standardized performance measurement |
| Formative Feedback System | Immediate structured instructor feedback using DOPS | Enhances reflective practice |
| Summative OSCE | Objective Structured Clinical Examination across 5 stations | Valid and reliable competency evaluation |
| Reflective Debriefing | Guided reflection after simulation | Consolidation of clinical reasoning |

**2.4 Instruments and Measures**

Clinical competency was assessed using multiple complementary tools to ensure triangulation and measurement validity.

Table 3. Outcome measures and psychometric properties

| Instrument | Purpose | Items | Reliability | Validity |
|---|---|---|---|---|
| OSCE (5 stations) | Summative competency performance | 25 checklist indicators | Cronbach's α = 0.89 | Content validity (CVI = 0.92) |
| DOPS Rating Scale | Direct procedural observation | 12 criteria | Inter-rater ICC = 0.87 | Expert validated |
| Clinical Self-Efficacy Scale | Confidence in performing skills | 18 Likert items | Cronbach's α = 0.91 | Construct validity (CFA fit indices: CFI = 0.94; RMSEA = 0.05) |

Content validity was calculated using item-Level CVI (I-CVI) and Scale-Level CVI (S-CVI). Items with I-CVI < 0.78 were revised. Construct validity of the self-efficacy scale was examined using confirmatory Factor Analysis (CFA).

**2.5. Data Collection Procedures**

During the intervention phase, the experimental group underwent a structured 8-week competency-based clinical skills program consisting of weekly 3-hour sessions integrating simulation, guided supervision, and formative assessment. The control group received conventional clinical instruction based on existing curriculum structures. Pre-test competency measurements were conducted one week before the intervention. Post-test assessments were administered immediately after completion, with a retention test conducted four weeks later to evaluate skill sustainability.

**2.6 Data Analysis**

Qualitative data from Phase 1 were analyzed using thematic analysis supported by NVivo software (Version 14). Coding was conducted independently by two researchers, and intercoder agreement reached 0.85 before consensus refinement.

Quantitative data were analyzed using SPSS Version 27. Normality was assessed via Shapiro–Wilk tests. Independent t-tests and ANCOVA were performed to compare post-test scores while controlling for baseline differences. Effect sizes were calculated using Cohen's d. Statistical significance was set at $p < 0.05$. Additionally, internal consistency reliability was examined using Cronbach's alpha, and inter-rater reliability for OSCE and DOPS was assessed using Intraclass Correlation Coefficient (ICC).

Implementation fidelity was monitored using a structured observation checklist completed by two independent observers. Fidelity scores averaged 93%, indicating high adherence to the designed protocol. Following pilot testing and statistical evaluation, minor revisions were made to rubric wording clarity and feedback timing structure before finalizing the clinical skills competency development model.

**2.7 Ethical Considerations**

Ethical approval was obtained from the Institutional Research Ethics Committee of the university (Approval No. TU-REC/2024/091), and all participants provided written informed consent.

## 3. RESULTS AND DISCUSSION

A total of 94 participants were involved across all research phases. In Phase 1 (needs assessment), 24 nursing assistant students and 6 clinical instructors participated. In the effectiveness phase (Phase 5), 64 second-year nursing assistant students were included and allocated into an intervention group (n = 32) and a control group (n = 32). No participants withdrew during the intervention period.

The demographic characteristics of students in the effectiveness phase are presented in table 4. There were no statistically significant differences between groups at baseline, indicating comparability prior to intervention.

Table 4. Baseline Characteristics of Participants

| Variable | Intervention (n=32) | Control (n=32) | p-value |
|---|---|---|---|
| Mean age (years) | 21.8 ± 1.4 | 22.1 ± 1.6 | 0.41 |
| Female (%) | 81.3% | 78.1% | 0.76 |
| Prior clinical placement (months) | 4.2 ± 1.1 | 4.0 ± 1.3 | 0.53 |

| Variable | Intervention (n=32) | Control (n=32) | p-value |
|---|---|---|---|
| Baseline OSCE score (0–100) | 61.7 ± 6.8 | 62.3 ± 7.1 | 0.72 |
| Baseline self-efficacy (0–100) | 58.4 ± 8.2 | 57.9 ± 7.9 | 0.83 |

Table 4 presents the baseline characteristics of participants in the intervention (n=32) and control groups (n=32). The groups were comparable in terms of mean age, gender distribution, prior clinical placement duration, baseline OSCE scores, and self-efficacy levels, with no statistically significant differences observed (all $p > 0.05$). This indicates that both groups were well balanced before the intervention.

### 3.1 Phase 1: Needs assessment findings

Thematic analysis identified three major competency gaps:

1. Inconsistent psychomotor skill execution (particularly wound dressing and safe patient mobilization)
2. Limited structured feedback during clinical placements
3. Absence of standardized performance rubrics

Students reported variability in instructor expectations and assessment transparency. Clinical instructors highlighted the lack of validated competency indicators specific to nursing assistant scope of practice. These findings informed the development of a structured competency-based clinical skills model integrating simulation, standardized rubrics, and DOPS-based feedback. Intercoder reliability for qualitative coding reached $\kappa = 0.85$, indicating strong agreement.

### 3.2 Phase 2: Expert validation of the developed model

Seven experts in nursing education and clinical supervision evaluated the model. The overall Scale-Level Content Validity Index (S-CVI) was 0.92, exceeding the acceptable threshold of 0.80.

Table 5. Content validity results

| Component | I-CVI Range | Decision |
|---|---|---|
| Simulation structure | 0.86–1.00 | Retained |
| Competency rubric clarity | 0.83–0.94 | Minor revision |
| DOPS feedback format | 0.89–1.00 | Retained |
| OSCE station alignment | 0.90–1.00 | Retained |
| Reflective debriefing guide | 0.82–0.93 | Minor revision |

Minor wording refinements were made to rubric descriptors to improve clarity and feasibility.

### 3.3 Phase 3: Implementation fidelity

The 8-week structured intervention demonstrated high adherence to protocol. Mean fidelity score across observed sessions was 93% (range 89–97%). No major deviations from the instructional design were identified.

### 3. 4 Phase 4: Effectiveness evaluation

Clinical competency outcomes (OSCE), Post-intervention OSCE scores significantly improved in intervention group compared to the control group.

Table 6. Comparison of OSCE Scores

| Measure | Intervention | Control | p-value | Effect Size (d) |
|---|---|---|---|---|
| Pre-test | 61.7 ± 6.8 | 62.3 ± 7.1 | 0.72 | – |
| Post-test | 82.6 ± 5.9 | 69.4 ± 6.7 | <0.001 | 1.95 |
| Retention (4 weeks) | 79.8 ± 6.3 | 66.1 ± 7.0 | <0.001 | 1.78 |

Direct observation of procedural skills (DOPS) ratings were significantly higher in intervention group (mean = 4.3 ± 0.4) compared to the control group (3.5 ± 0.5) on a 5-point scale ($p < 0.001$).
Inter-rater reliability for DOPS was high (ICC = 0.87).

### 3. 5 Self-Efficacy Outcomes

Self-efficacy scores demonstrated significant improvement in the intervention group.

Table 7. Self-Efficacy Comparison

| Measure | Intervention | Control | p-value |
|---|---|---|---|
| Pre-test | 58.4 ± 8.2 | 57.9 ± 7.9 | 0.83 |
| Post-test | 81.1 ± 7.5 | 64.3 ± 8.1 | <0.001 |
| Retention | 78.6 ± 7.8 | 62.5 ± 8.4 | <0.001 |

Cohen's d for post-test self-efficacy difference = 2.09 (very large effect). Confirmatory factor analysis supported construct validity (CFI = 0.94; RMSEA = 0.05). A repeated-measures ANOVA within the intervention group demonstrated sustained performance from post-test to retention test (p = 0.08), indicating no significant decline in competency over four weeks. In contrast, the control group showed a statistically significant decline (p = 0.02). Overall, the developed competency-based model resulted in:

Table 8. Summary of quantitative impact of the competency-based clinical skills development model

| Outcome Variable | Baseline Mean ± SD | Post-Intervention Mean ± SD | Absolute Change | Percentage Increase | Effect Size (Cohen's d) | Statistical Significance |
|---|---|---|---|---|---|---|
| OSCE Performance Score (0–100) | 61.7 ± 6.8 | 82.6 ± 5.9 | +20.9 | +33.9% | 1.95 | p < 0.001 |
| Clinical Self-Efficacy (0–100) | 58.4 ± 8.2 | 81.1 ± 7.5 | +22.7 | +38.9% | 2.09 | p < 0.001 |
| DOPS Rating (1–5 scale) | 3.4 ± 0.5 | 4.3 ± 0.4 | +0.9 | +26.5% | 1.76 | p < 0.001 |
| Skill Retention (OSCE at 4 weeks) | 61.7 ± 6.8* | 79.8 ± 6.3 | +18.1 | +29.3% | 1.78 | |

Table 8. Consolidated quantitative impact of the competency-based clinical skills development model demonstrating statistically significant improvements across all measured domains with large effect sizes. This study developed and empirically validated a competency-based clinical skills development model tailored for nursing assistant students within a university setting. The findings demonstrate statistically significant and educationally meaningful improvements in clinical performance, procedural competence (DOPS), self-efficacy, and short-term skill retention [41], [42]. The large effect sizes observed across all outcome variables suggest that the structured integration of simulation, standardized competency rubrics, and formative feedback mechanisms produces a robust instructional impact beyond conventional apprenticeship-based training.

The findings align strongly with the principles of competency-based education (CBE), which emphasize observable performance, criterion-referenced assessment, and mastery-oriented progression rather than time-based instruction. CBE posits that learning effectiveness depends on clearly defined competencies, structured feedback, and authentic performance evaluation [43]. In the present study, the integration of competency mapping, structured simulation modules, and validated assessment tools operationalized these theoretical foundations in a context-specific manner. The significant improvement in OSCE scores and DOPS ratings indicates that aligning instructional activities with measurable competency indicators enhances performance reliability and clinical readiness [44].

International literature has consistently reported that simulation-based learning combined with structured feedback improves psychomotor performance and clinical reasoning in nursing education. However, most prior studies Guzik and Więckowska [45] have focused on registered nurses or undergraduate nursing students, with limited attention to nursing assistant education pathways . The present study addresses this gap by demonstrating that competency-based frameworks can be successfully adapted to the scope of practice and training level of nursing assistant students [46]-[48]. In particular, the sustained performance at four-week retention testing suggests that deliberate practice and reflective debriefing may strengthen long-term skill consolidation, supporting experiential learning theory and mastery learning principles [49], [50].

A critical contribution of this research lies in addressing the methodological gap in development-oriented nursing education studies [51]. While competency frameworks are widely advocated in policy and curriculum documents, relatively few studies integrate systematic needs assessment, expert validation, pilot testing, and quasi-experimental effectiveness evaluation within a single coherent research design [52]-[54]. By employing a Design and Development Research (DDR) approach, this study moves beyond descriptive competency identification toward the production of an empirically tested, transferable instructional model [55], [56]. This integration of qualitative exploration and quantitative validation enhances internal coherence and strengthens the evidentiary basis for curriculum reform.

The novelty of this study is threefold. First, it provides a contextually grounded competency-based clinical skills model specifically designed for nursing assistant students, a population often underrepresented in high-impact educational research. Second, it operationalizes CBE principles into a measurable and validated assessment system incorporating OSCE and DOPS tools adapted to the assistant-level scope of practice. Third, it demonstrates not only immediate competency gains but also measurable skill retention, addressing concerns regarding short-lived simulation effects frequently reported in the literature [57], [58]. These elements

collectively contribute to advancing competency-based clinical education research in mid-level health workforce training.

The educational implications are substantial. At the curricular level, the model offers a structured framework that aligns learning objectives, instructional strategies, and performance assessments within a unified competency architecture. This alignment enhances transparency, fairness, and standardization in clinical evaluation. At the institutional level, the integration of validated rubrics and structured feedback mechanisms may reduce variability in instructor judgment and improve assessment reliability [59], [60]. From a workforce perspective, strengthening clinical competence among nursing assistants supports patient safety initiatives, reduces procedural errors, and enhances interprofessional collaboration in healthcare settings. Given the increasing reliance on mid-level care providers in ageing European health systems, structured competency development models represent a strategic investment in healthcare quality assurance.

Despite its strengths, this study has limitations that warrant consideration. First, the quasi-experimental design, although robust, did not employ random allocation, which may limit causal inference. Second, the study was conducted within a single institutional context, potentially affecting generalizability to other educational or healthcare systems. Third, the retention period was limited to four weeks longer follow-up intervals would provide stronger evidence regarding long-term skill sustainability. Additionally, while psychometric validation demonstrated strong reliability and content validity, future research should incorporate multi-institutional validation and structural equation modeling to further confirm construct robustness.

In conclusion, this study provides empirical evidence that a systematically developed competency-based clinical skills model can significantly enhance performance, confidence, and skill retention among nursing assistant students. By bridging theoretical principles of CBE with validated instructional design and measurable outcomes, the study contributes to advancing evidence-based clinical education for the mid-level healthcare workforce. Strengthening competency development in nursing assistant education is not merely a pedagogical refinement but a necessary response to evolving healthcare demands and patient safety imperatives.

## 4. CONCLUSION

This study aimed to develop and validate a competency-based clinical skills development model for nursing assistant students and to evaluate its effectiveness in improving clinical performance, procedural competence, and self-efficacy. The findings confirm that the systematically designed model produced statistically and practically significant improvements across all outcome measures. Students who received the intervention demonstrated a 33.9% increase in OSCE performance scores (from 61.7 to 82.6; $p < 0.001$; $d = 1.95$), significantly higher DOPS ratings (4.3 vs. 3.5; $p < 0.001$), and a 22.7-point increase in self-efficacy ($p < 0.001$; $d = 2.09$) compared to the control group. Importantly, competency gains were sustained at four-week retention testing (79.8 vs. 66.1; $p < 0.001$), indicating that the model supported not only immediate skill acquisition but also short-term competency stability. These results demonstrate that aligning structured simulation, standardized competency rubrics, formative DOPS-based feedback, and summative OSCE assessment within a unified framework effectively operationalizes competency-based education principles in nursing assistant training. Future research recommendations include expanding longitudinal follow-up to evaluate long-term clinical transferability, conducting multi-institutional validation, and examining scalability across healthcare education systems.

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## USE OF ARTIFICIAL INTELLIGENCE (AI)-ASSISTED TECHNOLOGY

The authors confirm that no artificial intelligence (AI)-assisted technologies were utilized in the preparation, analysis, or writing of this manuscript. All stages of the research process, including data collection, data interpretation, and the development of the manuscript, were conducted solely by the authors without any support from AI-based tools.

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