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Integrating the fundamental of care framework in the undergraduate nursing curriculum: A randomized, controlled, and multicentric study

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ABSTRACT

Background: Fundamentals of Care (FoC) are often perceived as "invisible" and of lesser clinical relevance, especially among nursing students. Evidence on how to integrate the FoC Framework into undergraduate education and assess its impact remains scarce.

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Aim: To assess the effectiveness of integrating the FoC Framework into a three-year undergraduate nursing curriculum on students' clinical reasoning, technical and relational competencies and patient-reported experiences of care.
Design: Multicentric randomized study following first-year students through their third year.
Methods: The experimental group followed an FoC-informed integrated curriculum; the control group the standard one. Assessments included the Triple Jump test and Objective Structured Clinical Examination. Additional data were collected on patient perception and students' learning approaches.
Results: A total of 234 students were enrolled across four universities, with 150 progressing to year two and 79 to year three. The intervention group consistently achieved higher Triple Jump scores in the second and third years ($p < .05$) and higher Objective Structured Clinical Examination scores across all three years, both pre- and post-placement ($p < .05$). Relational skills scores were also higher in the third year. No significant differences were found in patient-reported experiences of care or in students' learning approaches.
Conclusions: Integration of the FoC Framework into the curriculum enhanced clinical reasoning and improved early technical and relational performance, although these gains were not reflected patient-reported outcomes. Future studies should consider involving the broader healthcare team to support a more effective and sustained transfer of FoC principles into clinical practice.

1. Introduction

Fundamentals of Care (FoC) (Abbreviations: FOC: Fundamentals of Care; OSCE: Objective Structured Clinical Examination; FoC-PP: FoC – Practice Process; PBL: Problem-Based Learning) refer to the professional activities aimed at addressing patients' essential needs, which, when met promptly, uphold their safety and dignity (Watson, 2019). FoC also promotes physical and psychological well-being by fostering positive and trusting relationships among nurses, patients and families (Feo et al., 2018b).

The FoC framework provides one of the most comprehensive models for articulating how nurses deliver fundamental care and how contextual factors shape its quality. It conceptualizes care across interconnected dimensions: establishing a trusting nurse–patient relationship, integrating physical and psychosocial needs and recognizing how the care context influences practice. Together, these dimensions offer clear guidance for teaching and assessing fundamental care competencies. (Kitson and Muntlin Athlin, 2013).

Although essential for daily patient care, such as hygiene, nutrition, mobility and communication, FoC activities are often the first to be compromised or overlooked in clinical settings (Kitson et al., 2010). Approximately 40 % of missed nursing care involves FoC activities (Bagnasco et al., 2017). Since the seminal work of Kitson et al. (2010), attention to this issue has expanded across diverse care settings and in nursing education both internationally (Ekermo et al., 2023; Lewis et al., 2018; Naughton et al., 2024; Thillainadesan et al., 2023) and nationally (Bagnasco et al., 2017, 2022a; Chiappinotto et al., 2025; Ottonello et al., 2023), underscoring the centrality of FoC to professional nursing and care quality.

These challenges are particularly evident in contexts where nursing is narrowly framed as a set of technical tasks rather than a relational, patient-centered profession (Feo and Kitson, 2016). In such environments, FoC is often insufficiently incorporated into care plans (Bagnasco et al., 2020), either because specialized tasks are prioritized or because FoC is perceived as outside the nurse's focus, leading to its implicit transfer to healthcare assistants (Feo and Kitson, 2016). Consequently, activities requiring technical specificity are routinely prioritized over relational and fundamental care (Kalisch and Xie, 2014; Orique et al., 2017).

This undervaluation highlights an educational gap: FoC is often addressed implicitly, without a coherent framework linking theory and practice. (Feo et al., 2019; Palese et al., 2020). Recent evidence also points to the need for systematic approaches to teaching and evaluating students' fundamental care competence as part of broader educational leadership strategies (Nowell et al., 2023). This educational gap is closely linked to how students learn to identify and respond to fundamental care needs during their clinical training.

There is a deep connection between addressing fundamental needs in clinical settings and the way nursing education prepares students to recognize and respond to these needs (Feo and Kitson, 2016). This connection becomes especially significant when considering the influence of role models encountered during training, as the behaviors and attitudes displayed by nurses shape students' perceptions of care and may indirectly contribute to their long-term professional development. In this context, the inclusion of trained clinical preceptors plays a crucial role, as effective supervision can help students bridge theoretical knowledge with practice. Although constructs such as professional identity or professional development were not outcomes of this study, the literature indicates that supportive supervision can facilitate students' engagement with fundamental care principles (Galletta et al., 2024).

However, educational strategies to effectively convey FoC to nursing students remain insufficiently explored (Feo et al., 2018a) and many undergraduate programs still place limited emphasis on these core aspects, reflecting their marginalization in clinical practice (MacMillan K., 2016). As a result, students may receive limited instruction on essential FoC activities, shaped by contextual factors affecting both the curriculum and clinical placements (Feo et al., 2019).

Clinical internships play a crucial role in students' professional development, offering opportunities to engage directly with real-world care settings. However, these experiences often unfold within contexts dominated by a biomedical model, where technical and administrative tasks are prioritized (Feo and Kitson, 2016). Within this framework, responsibility for providing FoC is frequently shifted, often implicitly, to healthcare assistants (Allan and Smith, 2010; Chapman and Clucas, 2014). This dynamic shapes how students perceive the ownership and value of FoC and may limit the extent to which these aspects become integrated into their professional identity.

Integrating the FoC Framework into nursing education offers a structured approach to support the progressive development of professional competence. Evidence shows that combining theoretical instruction with clinical practice, guided reflection and deliberate pedagogical strategies enables students to critically assess their own performance and connect caring principles to practice (Lundell Rudberg, et al., 2022).

Furthermore, a recent review highlights educational strategies, such as curriculum scaffolding, simulation-based learning and guided clinical supervision. These approaches foster clinical thinking, clinical judgment and relational competence and support the internalization of core nursing values and holistic professional practice (Hobenu et al., 2025). In this way, the FoC Framework serves as both a theoretical and practical guide, bridging classroom learning with clinical application while reinforcing students understanding of the relational dimension of care.

In addition to student-centered outcomes, this study also considered patients' and families' perceptions of care. This choice reflects the relational dimension of the FoC Framework, recognizing that the ultimate indicator of educational effectiveness is not only students'

technical proficiency but also their ability to deliver person-centered, compassionate care as perceived by patients. Patient-reported experience thus serves as a meaningful indicator of how learning is translated into practice. Building on this evidence, the present study evaluates whether systematically embedding the FoC Framework in undergraduate nursing education enhances students' competence development and supports the delivery of high-quality, person-centered care during clinical placements.

2. Aim and research question

The aim of this study was to evaluate the effectiveness of integrating the FoC framework into the undergraduate nursing curriculum, with a specific focus on its impact on nursing students' clinical reasoning, technical and relational skills and on patients' perceptions of the quality of care received.

To address this aim, the following research questions were formulated:

- Does the integration of the Fundamentals of Care Framework into undergraduate nursing education improve nursing students' clinical reasoning, technical and relational skills compared with the standard curriculum?
- How do students perceive their learning of FoC-related competencies across classroom and internship settings?
- How do patients and their families perceive the outcomes of care provided by students trained with the FoC-based curriculum, particularly in meeting fundamental care needs?

3. Materials and methods

3.1. Study design

This multicentre, randomized, controlled study followed a cohort of first-year undergraduate nursing students across four Northern Italy universities throughout their three-year bachelor's program. The study was registered at ClinicalTrials.gov (NCT05177627) and adhered to CONSORT guidelines (Schulz et al., 2010). The present manuscript reports the final outcomes, related to student performance in theoretical, simulated and clinical-skill assessment (Triple Jump and OSCE), as well as patient and family feedback on how well students met fundamental care needs (Bagnasco et al., 2024).

3.2. Population

3.2.1. Student level

All first-year undergraduate nursing students enrolled in the academic year 2021/2022 at the participating universities were invited to take part in the study. After receiving detailed information about the study aims and procedures, only students who provided written informed consent were enrolled and subsequently followed longitudinally through their third year of training.

3.2.2. Clinical preceptor level

All nurses serving as clinical preceptors in the first-year internship settings were invited to participate after receiving information about the study and providing written informed consent. Preceptors working in units allocated to the intervention group received standardized training on the FoC-framework, whereas preceptors in control units followed usual supervisory practices. Each student was paired with a dedicated preceptor in a 1:1 supervision model.

3.2.3. Patient and family members

Patients and, when applicable, family members who had direct care interactions with participating students during clinical placements were eligible. Inclusion criteria were: age $\geq$18 years, ability to provide informed consent and direct interaction with a student. Exclusion criteria included cognitive impairment, clinical instability, or inability to understand the questionnaire items and provide meaningful responses. When physical limitations prevented independent completion, participants could receive assistance from a caregiver or from non-supervising staff.

Eligible individuals were approached consecutively by a nurse or by a non-supervising student to minimize potential bias and written informed consent was obtained prior to participation. To ensure anonymity and reduce respondent burden, no individual demographic or baseline data were collected from patients or family members.

3.2.4. Study setting

The study was conducted in two main settings:

(1) university classrooms and simulation laboratories, where theoretical instruction and practical training took place.

(2) clinical units in hospital or comparable healthcare facilities, where students completed their internships. A total of 40 medical or medical-affiliated units were included, accounting for approximately 920 hospitalized patients overall (mean of 23 per unit per day).

3.3. Sampling and randomization

3.3.1. Student level

Students were recruited as a convenience sample and, after enrollment, were randomly assigned to the intervention or control group using a web-based randomization tool (PickerWheel.com,). Randomization was performed separately in each campus, resulting in a stratified randomization procedure to ensure balanced distribution across sites.

3.3.2. Clinical unit level

Clinical departments were selected via probabilistic sampling and assessed for homogeneity in patient characteristics and work organization. Units were then randomized 1:1 to intervention or control using PickerWheel.com, with allocation performed independently by the coordinating center. After randomization, 21 units were allocated to the intervention group and 19 to the control group. The two groups were comparable in baseline characteristics: intervention units had 445 beds and control units 475 beds (mean 21.2 vs 25 beds per unit), the mean patient age was similar (70.9 vs 70.83 years) and a task-based organizational model was present in 5 units in each group.

3.3.3. Alignment of students and units

To maintain intervention fidelity, students assigned to the FoC-based curriculum were placed exclusively in intervention units, while students in the control curriculum were allocated solely to control units.

3.4. Blinding

Blinding of students, preceptors, or faculty was not feasible due to the educational nature of the intervention

3.5. Instruments

Outcome measures for both groups were collected using instruments adapted to maintain full consistency with the Fundamentals of Care Framework, by integrating FoC principles into item descriptors, prompts and performance criteria.

3.5.1. Classroom learning assessment of FoC

At the end of classroom instruction, clinical reasoning and problem-solving skills were assessed using the Triple Jump (Sasso and Gamberoni, 2003). Students worked through a clinical case that required them to formulate hypotheses, gather information, identify problems, establish a diagnosis, define goals and plan care. The scoring criteria were calibrated to reflect expected learning progression across the three years. In year

one, greater weight was assigned to problem identification and diagnosis (7 points each), while goal setting and care planning were weighted at 3 points each, whereas the weighting was reversed in year three to emphasize higher-order planning skills. Hypothesis formulation and information seeking remained constant at 5 points. Total score: 30 points.

3.5.2. Student perception assessment of FoC learning

Students' perceptions of where and how they learned FoC-related competencies (classroom vs. internship) were assessed using the *Basic Care Revisited Fundamental of Care* questionnaire (Huisman-de Waal et al., 2018), translated and validated in Italian (Bagnasco et al., 2022b). The tool includes subscales focusing on communication and nutrition (Catania et al., in submission for publication).

3.5.3. OSCE - technical and relational performances

Technical and relational skills were evaluated through Objective Structured Clinical Examination (OSCE) (Bagnasco et al., 2016). Each OSCE consisted of multiple stations, each supported by an ad-hoc checklist based on updated procedural evidence. Technical performance at each station was scored from 0 to 30, while relational skills were evaluated using the Guilbert communication grid (Guilbert, 2002; Guilbert, 1990), which assesses terminology, listening and clarity and provides a score ranging from –8 to + 8. The total OSCE score corresponded to the sum of the scores obtained across all stations. OSCEs were administered pre- and post-internship in all three years of the program.

3.5.4. Patient experience: fundamental care survey tool

Patients' perception of care received were evaluated using a study-specific questionnaire focused covering: communication/education, relationships, nutrition/hydration, elimination and hygiene. Respondents indicated whether needs were present, addressed and satisfied, through yes/no items and Likert-scales (Catania et al., submitted for publication).

3.5.5. Inter-rater consistency

To promote consistency across sites, OSCE checklists, communication grids and Triple Jump scoring criteria were jointly reviewed and standardized. Periodic meetings to support uniform interpretation of criteria, although no formal inter-rater reliability statistics were computed.

3.5.6. Additional assessment of preceptors

Preceptor preparedness and perceptions were indirectly evaluated using the Nursing 14 Essential Care Investigation Tool, validated via expert review and Delphi methodology. Although not an outcome measure, it provided contextual information on readiness to support the FoC integration.

3.6. Procedures

Implementation of the Educational Intervention (Figure A1):

Faculty at each site were trained by the research team on the FoC Framework and on the standardized intervention package. Training focused on the conceptual foundations of the FoC model, its practical implementation and its educational relevance.

- Clinical preceptors in the intervention units then received structured training (December 2021 – February 2022) via seminars delivered in-person or online. This training deepened core FoC Framework concepts, clarified their application in clinical and educational contexts and introduced shared study objectives, learning tools and instructions for integrating FoC principles into student supervision. A shared bibliographic package on the FoC Framework was distributed to all sites to ensure a common conceptual grounding.
- Students in the intervention group received FoC-based theoretical-practical integration. In year one, this consisted of 12 additional hours of theory and 25 h of simulation delivered by trained faculty, employing classroom teaching, problem-based learning (PBL) and simulation of real-life scenarios. In the following years, FoC integration was implemented mainly through PBL. The control group followed the nationally regulated standard nursing curriculum.
- During internships, preceptors trained in the FoC Framework were expected to support students in recognizing and applying FoC principles in everyday patient care. Although reflective discussion was not formally standardized across sites, preceptors were encouraged to promote opportunities for students to reflect on how FoC principles informed their clinical decision and patient interaction.

3.7. Outcomes measures

The study did not include direct observation of students' performance in the clinical setting. Real-world application of fundamental care was therefore not assessed objectively; instead, clinical performance was measured through OSCEs and indirectly through patients' and families' perceptions of care received.

3.8. Primary outcome

The primary outcome was students' performance in clinical reasoning and technical/relational skills, assessed at different points of the curriculum:

- Clinical reasoning was evaluated through the Triple Jump at the end of the first-year theoretical FoC instruction and following PBL-based FoC activities in the second and third years.
- Technical and relational skills were assessed through OSCEs administered before the clinical internship (following simulation-based training) and after the clinical internship.

3.9. Secondary outcome

- Students' perception of their learning of FoC-related competencies across classroom and internship settings.
- Patients' and families' perceptions of how well fundamental care needs were identified and addressed by students during clinical practice. *Ethical Considerations*

Ethical approval was obtained from the institutional Ethics Committee (September 28, 2021; Protocol 501/2021 - DB id. 11882), in accordance with the Declaration of Helsinki (World Medical Association, 2024). All participants provided written informed consent.

3.10. Data analysis

Data were analyzed using Jamovi software (The Jamovi project, 2023). Continuous variables (Triple Jump and OSCE scores) were summarized as mean and standard deviations; categorical variables (Patient survey item, student perception items, nurse questionnaire items) as absolute and relative frequencies. Due to non-normal distribution, Mann-Whitney U tests were used for between-group comparisons of continuous variables ($p \leq 0.05$). For each between-group comparison, mean differences were reported together with their standard errors (SE) and corresponding p-values, as shown in the tables. Due to complete anonymization of student identifiers at each assessment point, individual longitudinal tracking was not possible. Therefore, repeated-measures analyses could not be performed and yearly cross-sectional comparisons between groups were conducted instead.

For the student perception questionnaire, differences between classroom and internship-based learning were computed and compared via *t*-tests; group differences in mean scores for each learning context

were also analysed using *t*-tests.

For patient survey data, responses were dichotomized into "satisfied" vs "not fully satisfied" and satisfaction frequencies were compared using Chi-square tests within each fundamental care need.

Analyses followed a per-protocol approach. Participants who did not complete an assessment were excluded from analyses for that specific outcome.

Sample Size

The sample size estimation was based on the primary endpoint, assuming an effect size of 0.4 in FoC- related student performance, $\alpha = 0.05$ and power = 0.80. A minimum of 200 students were required; to account for 20 % attrition, the final target sample was 240 students (120 per group).

4. Results

A total of 18 teaching centers affiliated with the four universities were invited to participate. Of the 251 students who consented, 234 were randomized into intervention and control groups, forming the first-year cohort. Participant numbers declined over the three-year period due to academic progression and attrition, resulting in 150 students assessed in the second year (60 %) and 79 in the third year (31 %) (Table A1). The CONSORT diagram (Figure A2) reports the recruitment, allocation and flow through the assessments.

4.1. Triple jump performance

Triple Jump assessments were conducted annually to evaluate students' clinical reasoning skills. In the first year, performance was comparable between the two groups (25.03 SD 5.31 vs 24.1 SD 5.40; $p = 0.075$), although the intervention group showed slightly better results in all items' scores.

In the second year, differences became more pronounced. Intervention students achieved higher overall scores (25.6 SD 4.00 vs 23.90 SD 4.53; $p = 0.025$), particularly in key domains such as hypothesis formulation and the identification of additional information needed to guide care planning.

By the third year, the intervention group demonstrated the clearest advantage. Their total scores were higher (26.10 SD 3.31 vs 24.20 SD 3.45; $p = 0.020$) and they outperformed the control group especially in additional information required and goal-referenced care interventions.

Taken together, Triple Jump results indicate a progressive larger between-group differences in clinical reasoning scores across the three years (Table A2).

4.2. Pre-internship OSCE performance

Pre-internship OSCEs were administered annually to assess students' technical and relational competencies before entering clinical placements.

In the first year, intervention students obtained higher total scores than controls (148 SD 26.80 vs 132 SD 37.20; $p = 0.002$), with significant differences across several procedures, including bed bath, blood pressure measurement and breath detection.

In the second year, the intervention group again achieved higher overall results (170 SD 17.10 vs 157 SD 23.10; $p = .001$). Differences involved both basic care tasks (bed bath, oral and perineal hygiene) and vital sign assessment.

In the third year, this pattern was confirmed (181 SD 10.60 vs 170 SD 16.10; $p = .003$). Higher scores for intervention students were observed in relational skills as well as in multiple assessment stations.

Across all three years, pre-internship OSCE scores were consistently higher in the intervention group across several technical and relational domains (Table A3).

4.3. Post-internship OSCE performance

Post-internship OSCEs allowed evaluation of how competencies were applied and consolidated during clinical placement.

In the first year, the intervention group achieved higher total scores (154 SD 28.73 vs 142 SD 34.10; $p = .012$), with notable differences in oral hygiene care, blood pressure measurement, breath detection and relational skills.

The second-year cohort showed a similar pattern (173 SD 19.01 vs 163 SD 20.55; $p = .003$). Intervention students performed better in both basic procedures (oral hygiene, perineal hygiene) and across all monitoring activities and vital-sign detection tasks.

In the third year, the difference remained stable, with intervention students achieving higher overall performance (183 SD 7.11 vs 177 SD 9.20; $p = .003$) and outperforming controls across several stations, including bed bath, oral hygiene, arterial pulse detection and communication-focused skills.

Overall, post-internship OSCE results confirmed a consistent and sustained advantage for students trained through FoC-integrated pathways across all three years (Table A4).

4.4. Secondary outcomes: student perceived learning and patient perceptions

Students' self-assessments of learning were collected annually.

In the first year ($n = 98$), the intervention group reported higher perceived learning in several classroom-related areas, such as safe care, medication administration, documentation of food intake and communication with informal caregivers, as well as in internship-related domains including nutritional care and patient communication. The control group, instead, reported higher perceived learning in respecting patient choices. Differences also emerged in preferred learning environments: the control group more often associated learning gains with classroom instruction, whereas the intervention group reported stronger outcomes during clinical placements, particularly in respiratory care, dignity-related care and malnutrition management.

In the third year ($n = 58$), the intervention group again reported higher perceived learning in internship-based areas, including nutritional assessment, communication, respect for patient preferences and elimination care. Conversely, the control group reported higher perceived learning in theoretical domains such as mobility, nutritional strategies, support for sexual expression and communication in pediatric settings.

Across the three years, 806 patient questionnaires were collected (control: $n = 324$; intervention: $n = 423$). No statistically significant differences emerged regarding unmet needs, care received, or satisfaction levels. The only exception occurred in the first year ($n = 345$), where the intervention group reported higher satisfaction with patient information ($p = 0.034$). No significant differences were found in the second ($n = 271$) or third year ($n = 189$).

5. Discussion

This study represents the first multicentric randomized controlled trial in Italy and one of the few internationally, to incorporate the Fundamentals of Care (FoC) framework into undergraduate nursing education, aiming to bridge the academic and clinical dimensions of professional training. By addressing a significant challenge identified by Kitson et al. (2025), the study contributes to the ongoing global discourse on bridging academic preparation and clinical realities through structured approaches to fundamental care.

The intervention was designed as a multi-faceted educational strategy that combined theoretical instruction, simulation-based learning and clinical practice. Implemented across four prominent nursing university centers in three Italian regions, the study followed CONSORT guideline and employed validated instruments that assessed clinical

reasoning (Triple Jump), as well as technical, relational and communication skills (OSCE) and patient-reported measures, thereby ensuring methodological rigor and strengthening the reliability of the findings.

Recognizing that educational transformation involves more than the transmission of knowledge and skills, the project also considered, at a complementary level, the role of clinical preceptors in supporting contextualized learning. In this capacity, preceptors helped bridge classroom instruction with the demands of clinical practice, facilitating students' ability to translate theoretical concepts into clinical reasoning. As noted in literature (Galletta et al., 2024), supervision can play a valuable role in connecting theoretical learning with decision-making processes, although this dimension was not assessed in the present study. Because the quality, consistency and fidelity of supervision were not formally assessed, variability in preceptors' preparedness or engagement may have contributed to differences across sites and this should be considered when interpreting between-site variation.

To address the persistent issue of the theory–practice gap, which contributes to transition shock during initial clinical experiences, the intervention sought to foster tighter collaboration between educational institutions and clinical settings. As highlighted by Tang et al. (2025), such partnerships are fundamental to developing a cohesive and responsive nursing education system.

This alignment is consistent with major international and European priorities, including WHO Europe's framework for action for the nursing workforce (World Health Organization, 2021) and the European Federation of Nurses Associations (EFN) competency framework (European Federation of Nurses Associations, 2015), both of which emphasize person-centered care, core nursing competencies and high-quality educational models.

Empirical findings indicated that students in the intervention group generally outperformed their peers. In the Triple Jump test, which assesses clinical reasoning and problem-solving, these students showed progressively higher scores across the three years. The statistically significant differences observed in the later years suggest a cumulative effect on clinical reasoning, a competency that is central to long-term professional development. This pattern is consistent with evidence reported by Voldbjerg et al. (2019), who emphasize how structured reasoning frameworks can strengthen students' ability to approach clinical situations systematically. In our study, the pedagogical setup not only supported the development of reasoning processes but also reinforced key elements of professional practice, particularly communication, relational engagement and respect for patient privacy, as similarly underscored by Nowell et al. (2023).

Comparative OSCE results before and after internships further confirmed the added value of the FoC-informed curriculum. Improvements were across technical and relational skills, particularly in the first year. Even modest differences carried educational relevance, signaling meaningful gains in readiness for practice and confidence in fundamental care delivery. Relational competencies remained a consistent area of differentiation between groups, emphasizing the FoC framework's potential to enhance patient-centered communication and emotional intelligence, as central to Kitson's work (Kitson, 2016, 2018).

Regarding students' learning approaches, no substantial between-group differences were observed. Although some statistically significant differences emerged at the item level, these were limited in proportion to the overall scale and should therefore be interpreted with caution. The general similarity in reported learning strategies reinforces the importance of understanding how students engage with diverse pedagogical approaches as highlighted by Panda et al. (2021).

Patient-reported outcomes revealed no significant differences across most fundamental care needs. Although intervention students consistently outperformed controls in OSCEs, these differences were not systematically reflected in patient experience, which is influenced by broader contextual elements such as staffing levels, ward routines and the organization of team-based care. During clinical placements, students participate meaningfully in direct care activities, yet their contribution is embedded within a wider multidisciplinary workflow. As a result, individual competencies may blend into team practices, reducing the visibility of student-specific effects and potentially attenuating measurable differences in patient perceptions. Nevertheless, integrating patient-reported measures remains a valuable, as it provides essential insights into the educational impacts from the patients' perspective and highlight the need for more sensitive and multidimensional instruments to capture subtle changes in fundamental care delivery.

While the present study was conceptually grounded in the FoC Framework, the project's implementation highlighted an additional opportunity: the usefulness of a more structured, practice-oriented process to support students and preceptors in translating the FoC principles into everyday clinical decision-making. This recognition emerged progressively throughout the project and informed subsequent developments.

Building on this momentum, a follow-up study conducted by the research team produced the first Italian translation, cultural adaptation and validation of both the FoC Framework and the FoC Practice Process (FoC-PP), using forward–backward translation, expert review, cognitive interviews and face-validity procedures (Bagnasco et al., 2025). This work now provides an important foundation for future applications and more systematically aligned evaluations, representing a significant methodological advancement in this study and offering a validated tool to support upcoming FoC-based educational implementations in Italy.

Overall, the study supports the potential of the FoC Framework as a lever for meaningful innovation in nursing education. The findings point to improvements in clinical reasoning as well as in technical and relational competencies. Moreover, the multicentric design and longitudinal approach contribute to narrowing the theory–practice gap and align with international calls for evidence-based, person-centered models of nursing education.

At the same time, the challenge of translating educational gains into measurable effects on patient-reported outcomes becomes evident, underscoring the need for further research.

6. Limitations

This study presents several limitations that should be acknowledged. Although descriptive cross-sectional information on clinical units (e.g., number of units, bed occupancy, mean patient age and organizational model) was available and confirmed the baseline comparability of intervention and control settings, no individual demographic or diagnostic data were collected from patients. Consequently, patient-reported experience could not be adjusted for individual characteristics and unmeasured clinical and contextual factors may have influenced responses.

Because student identifiers were anonymized at each annual assessment, it was not possible to link individual performances across years or conduct longitudinal analyses. Performance trends were therefore examined through independent cross-sectional comparisons, limiting interpretations of developmental trajectories.

In addition, sample attrition over the three-year period was substantial (66 %). Although all available data were analyzed per protocol, the loss of participants may have reduced statistical power and limited generalizability. Attrition was likely influenced by workload, voluntary withdrawal and the limited availability of clinical placements—particularly in smaller centers where students might return to the same clinical units across consecutive years. Missing-data management procedures or sensitivity analyses could not be applied due to the anonymized structure of the dataset.

Despite efforts to minimize contamination—such as randomizing clinical units and allocating FoC-trained preceptors exclusively to intervention units—informal exchanges between students or staff across units cannot be entirely ruled out and may have attenuated between-group differences.

Moreover, the study did not include a systematic assessment of preceptors' perceptions or supervisory experiences, which could have

provided additional contextual insight into students' learning processes.

Finally, patient-reported outcomes may have been influenced by contextual elements of the care environment, including multidisciplinary team dynamics and variability in students' exposure time, potentially obscuring the specific contribution of the FoC-based educational intervention.

7. Conclusions

This multicentric, three-year randomized controlled trial provides evidence that the systematic integration of the Fundamentals of Care (FoC) Framework into undergraduate nursing education is both feasible and educationally valuable. The findings suggest that embedding FoC principles in the curriculum can strengthen students' clinical reasoning and enhance technical, relational and communication competencies—core dimensions of person-centered nursing.

The findings support current international priorities, including WHO Europe's Framework for Action for the Nursing and Midwifery Workforce(World Health Organization, 2021) and the EFN Competency Framework, which call for educational models that promote holistic and relationship-based care. The results also highlight the crucial influence of clinical learning environments: organizational culture, supervisory practices and tutor engagement remain key determinants of how effectively students can apply FoC principles in practice.

Future development should focus on strengthening academic–clinical partnerships and expanding interprofessional learning opportunities to reinforce teamwork and shared responsibility for person-centered care. Further longitudinal research is also needed to explore how newly graduated nurses maintain and translate FoC principles into daily practice and how these competencies evolve during the transition to professional roles.

Overall, this study contributes to advancing evidence-based, person-centered nursing education and provides a foundation for future work aimed at consolidating FoC-informed competence development across diverse clinical settings.

Ethics Statement

This study was conducted in accordance with the principles outlined in the Declaration of Helsinki (World Medical Association, 2024) and ethical approval was granted by the Regional ethics committee on September 28, 2021 (501/2021 - DB id. 11882).

Ethical Considerations

Ethical approval for this study was obtained from the Territorial Ethics Committee of the Liguria Region, with a positive opinion (591/2021). Participants were thoroughly informed about the study's purpose, procedures, and their rights, including confidentiality and anonymity, which were ensured by using anonymous code. Participation was entirely voluntary, with the option to withdraw at any time without any consequences.

Data were securely stored and used exclusively for research purposes, in compliance with data protection regulations. Participants' informed consent was obtained in writing before their involvement, and they were given opportunities to ask questions and seek clarification throughout the study.

The study adhered to the principles outlined in the Declaration of Helsinki and relevant national ethical guidelines to uphold the highest standards of research integrity.

Acknowledgment of Sources

All content included in this article has been appropriately cited and any material from external sources has been reproduced with proper attribution and in compliance with copyright requirements.

Statistical analysis statement

The statistical analysis was performed by Cattani D. and Barbieri M. under the supervision of Catania G.

The authors affirm that the methods used in the data analyses are suitably applied to the data within the study design and context. We confirm that the statistical findings have been implemented and interpreted correctly.

The authors take full responsibility for ensuring that the choice of statistical approach is appropriate and for conducting and interpreting the analyses accurately.

Clinical Trial Registration

The study has been registered on ClinicalTrials.gov (NCT05177627).

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CRediT authorship contribution statement

Falbo Sara: Investigation. **Sasso Loredana:** Supervision, Methodology, Conceptualization. **Mazzoleni Beatrice:** Supervision, Methodology. **Zanini Milko:** Writing – review & editing, Methodology, Conceptualization. **Mansi Laura:** Investigation. **Montani Doriana:** Methodology, Investigation. **Bagnasco Annamaria:** Supervision, Project administration, Methodology, Conceptualization. **Cosmai Simone:** Methodology, Investigation. **Lusignani Maura:** Supervision, Methodology. **Catania Gianluca:** Writing – review & editing, Supervision, Methodology, Formal analysis, Data curation, Conceptualization. **Pagnucci Nicola:** Methodology, Conceptualization. **Milani Simona:** Investigation. **Cattani Daniela:** Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Data curation. **Casalino Monica:** Investigation. **Dal Molin Alberto:** Supervision, Methodology. **Cartabia Chiara:** Investigation. **Centanaro Roberta:** Methodology, Investigation. **Consolo Letteria:** Investigation. **Barbieri Martina:** Writing – review & editing, Writing – original draft, Visualization, Formal analysis, Data curation. **Tedi Sara:** Investigation.

Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the author(s) used ChatGPT (developed by OpenAI) to support the writing process by assisting with language refinement and content structuring. After using this tool, the author(s) carefully reviewed and edited the content as necessary and take full responsibility for the final version of the manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix

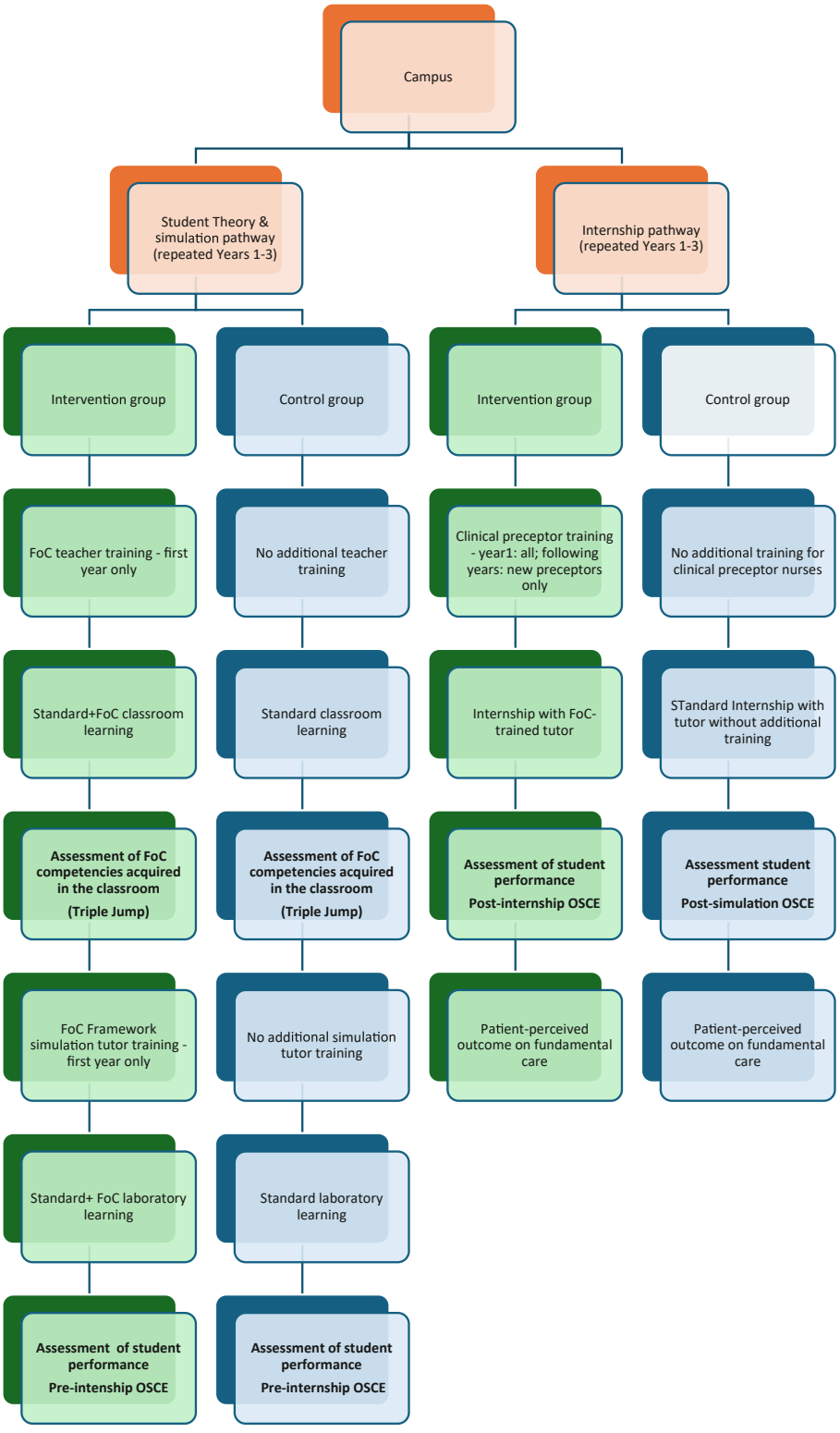

Figure A1. Flow diagram of study procedures showing three-year interventions and assessments for intervention and control groups. Theory and simulation components were completed first each year, followed by the clinical internship

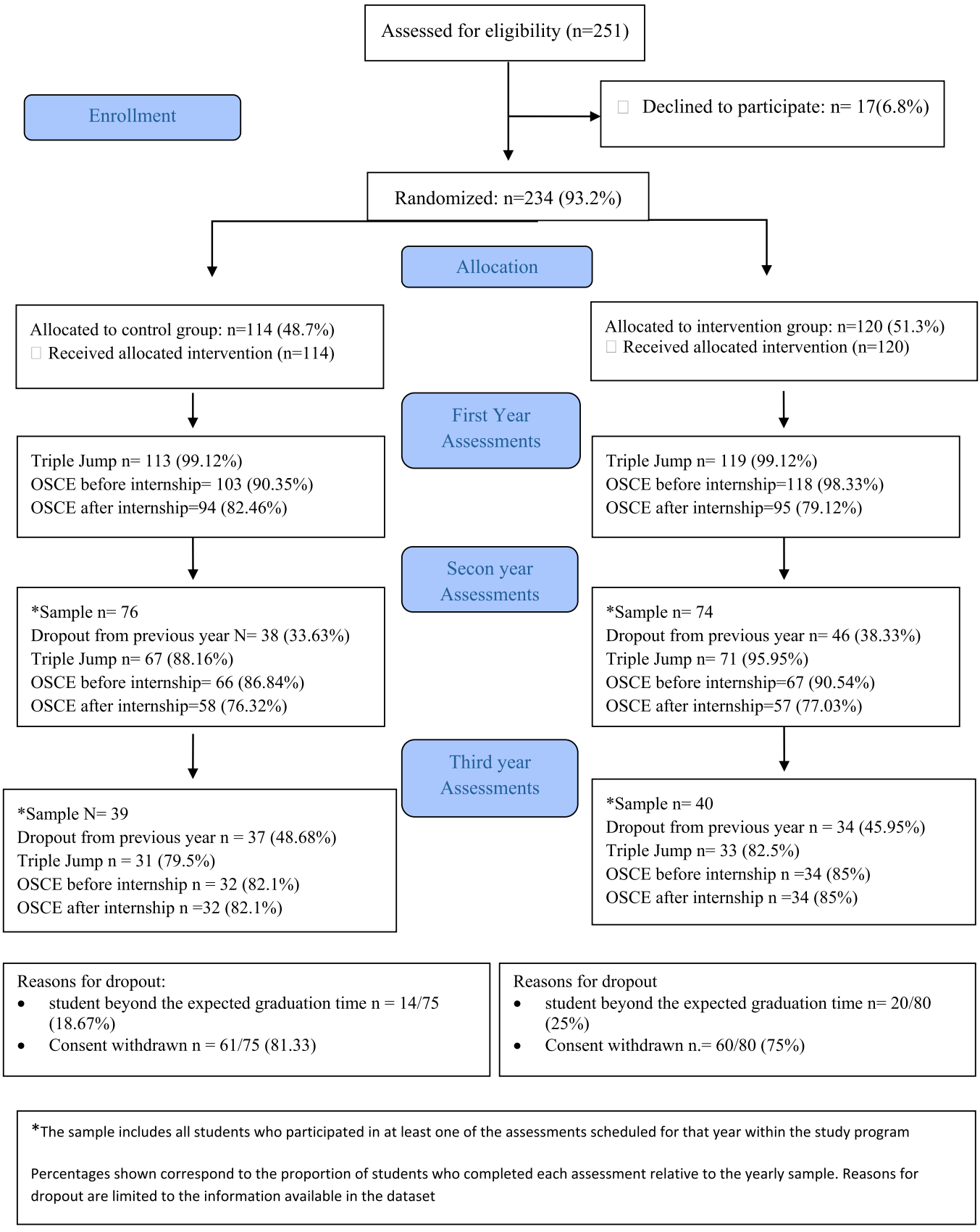

Figure. A2. CONSORT 2010 Flow Diagram

Table A1
Number of Students Enrolled per University Campus

University	Campus	Randomization			1st Year			2nd Year			3rd Year		
		C	I	tot	C	I	tot	C	I	tot	C	I	tot
University 1	1.1	10	10	20	10	10	20	2	2	4	1	2	3
	1.2	6	7	13	6	7	13	2	2	4	2	2	4
	1.3	10	10	20	10	9	19	10	5	15	10	4	13
	total	**26**	**27**	**53**	**26**	**26**	**52**	**14**	**9**	**23**	**13**	8	**21**
University 2	2.1	6	6	12	6	6	12	4	4	8	0	0	0
	2.2	5	4	9	5	4	9	0	0	0	0	0	0
	2.3	6	7	13	5	7	12	5	5	10	3	3	6
	2.4	5	6	11	5	6	11	4	6	10	2	3	5
	2.5	5	5	10	5	5	10	5	4	9	3	2	5
	2.6	9	9	18	9	9	18	8	8	16	3	1	4
	2.7	4	4	8	0	0	0	0	0	0	0	0	0
	total	**40**	**41**	**81**	**35**	**37**	**72**	**25**	**27**	**54**	**11**	9	**20**
University 3	3.1	5	5	10	4	4	8	3	4	7	3	4	7
	3.2	8	8	16	8	8	16	5	5	10	0	0	0
	3.3	10	10	20	8	10	18	8	8	16	5	4	9
	total	**23**	**23**	**46**	**20**	**22**	**42**	**16**	**17**	**33**	**8**	8	**16**
University 4	4.1	4	4	8	3	4	7	3	2	5	3	2	5
	4.2	11	12	23	11	11	22	7	7	14	1	5	6
	4.3	10	11	21	10	10	20	4	6	10	1	6	7
	4.4	4	5	9	4	5	9	4	4	8	2	2	4
	4.5	5	5	10	5	5	10	3	2	5	0	0	0
	total	**34**	**37**	**71**	**33**	**35**	**68**	**21**	**21**	**41**	**7**	15	**22**
TOTAL		123	128	251	114	120	234	76	74	150	39	40	79

C = Control group
I = Intervention group

Table A2
Triple Jump Assessment Results by Study Year and Group

Variable	Control Group			Intervention Group			Test of Significance[#]		
	Mean (SD)			Mean (SD)			Mean Difference ± SE (p)		
Triple Jump Item*	**I Year (N = 113)**	**II Year (N = 67)**	**III Year (N = 31)**	**I Year (N = 119)**	**II Year (N = 71)**	**III Year (N = 33)**	**I Year**	**II Year**	**III Year**
Hypotheses on the Etiology of the Symptom	4.42 ±1.03	4.16 ±1.25	4.28 ±1.10	4.50 ±1.12	4.62 ±0.72	4.23 ±0.97	-0.09 ± 0.14 (.220)	-0.46 ± 0.17 **(.035)***	0.05 ± 0.3 (.670)
Additional Information Required	3.75 ±1.71	4.04 ±1.21	4.13 ±1.12	4.08 ±1.58	4.39 ±1.03	4.64 ±0.65	-0.33 ± 0.22 (.074)	**-0.35 ± 0.19 (.039)***	**-0.51 ± 0.23 (.030)***
Nursing Care Issues	6.39 ±1.24	3.15 ±1.73	2.61 ±0.76	6.55 ±1.32	3.30 ±1.53	2.76 ±0.50	-0.16 ± 0.17 (.210)	-0.15 ± 0.28 (.190)	-0.15 ± 0.16 (.590)
Diagnosis	5.49 ±2.21	3.04 ±1.66	2.84 ±1.13	5.74 ±2.11	2.94 ±1.54	2.94 ±0.93	-0.24 ± 0.28 (.380)	0.10 ± 0.27 (.870)	-0.1 ± 0.26 (.820)
Diagnosis-Related Care Goals	2.06 ±1.04	4.63 ±1.87	5.42 ±1.69	2.18 ±1.09	4.92 ±1.81	6.00 ±1.17	-0.12 ± 0.14 (.230)	-0.29 ± 0.31 (.400)	-0.58 ± 0.36 (.250)
Goal-Referenced Care Interventions	2.03 ±1.07	4.91 ±1.90	4.68 ±1.74	2.28 ±0.99	5.46 ±1.61	5.88 ±1.41	-0.25 ± 0.14 (.0520)	-0.55 ± 0.30 (.093)	**-1.2 ± 0.40 (.004)***
Total Score	24.1 ±5.40	23.90 ±4.53	24.20 ±3.45	25.03 ± 5.31	25.60 ±4.00	26.10 ±3.31	-1.19 ± 0.70 (.075)	**-1.69 ± 0.73 (.025)***	**-1.9 ± 0.85 (.020)***

*Note: Each Triple Jump item score ranges from 0 to 5; total score ranges 0–30. A higher score means a better performance test
1st year: N = 232; 2nd Year: N = 138; 3rd year: N = 64
Mean differences is Control Group-Intervention group within year of course between study group, a negative sign indicates better performance in the intervention group
Statistical significance was assessed using the Mann-Whitney *U* test.
* $p < .05$ (Mann-Whitney U)

Table A3
OSCE Assessment Results Before Clinical Placement by Study Year and Group

Variable	Control Group			Intervention Group			Test of Significance[#]		
	Mean ±SD			Mean ±SD			Mean Difference ± SE (p)		
OSCE* Pre − internship Simulation	**I Year ±N = 103**	**II Year ±N = 66**	**III Year ±N = 32**	**I Year ±N = 118**	**II Year ±N = 67**	**III Year ±N = 34**	**I Year**	**II Year**	**III Year**

(*continued on next page*)

Table A3 (*continued*)

Variable	Control Group			Intervention Group			Test of Significance[#]		
	Mean ±SD			Mean ±SD			Mean Difference ± SE (p)		
Check List — Bed Bath	17.80 ± 14.45	25.80 ± 4.08	26.90 ± 3.91	23.70 ± 5.73	28.00 ± 3.07	28.90 ± 2.15	**−5.90 ± 1.45 (<.001*)**	**−2.15 ± 0.63 (<.001*)**	**−1.98 ± 0.77 (.016*)**
Check List — Oral Cavity Hygiene	22.90 ± 7.26	23.90 ± 5.25	26.90 ± 3.44	24.50 ± 5.91	26.90 ± 3.8	29.10 ± 1.37	−1.60 ± 0.89 (.150)	**−2.96 ± 0.79 (<.001*)**	**−2.15 ± 0.64 (.011*)**
Check List — Perineal Hygiene	23.7 ± 5.51	26.90 ± 2.99	27.20 ± 3.59	24.90 ± 5.52	27.90 ± 4.12	29.10 ± 2.28	−1.21 ± 0.74 (.057)	**−1.00 ± 0.63 (.003*)**	**−1.90 ± 0.74 (.005*)**
Check List — Arterial Pulse Detection	22.50 ± 11.05	26.00 ± 4.31	27.90 ± 3.17	24.10 ± 6.64	27.80 ± 2.78	29.00 ± 2.15	−1.68 ± 1.21 (.170)	**−1.73 ± 0.63 (.032*)**	**−1.12 ± 0.66 (.038*)**
Check List — Blood Pressure Measurement	22.80 ± 6.15	25.60 ± 4.66	27.60 ± 2.58	24.50 ± 5.00	26.90 ± 3.31	28.60 ± 2.63	**−1.73 ± 0.75 (.024*)**	−1.39 ± 0.67 (.140)	**−0.96 ± 0.64 (.047*)**
Check List — Breath Detection	19.70 ± 8.5	23.8 ± 7.39	27.80 ± 3.57	22. 20 ± 9.82	27.00 ± 4.15	29.20 ± 2.00	**−2.50 ± 1.24 (.010*)**	**−3.20 ± 1.04 (.011*)**	−1.32 ± 0.71 (.070)
Check List — Relational Skills assessment	2.41 ± 4.88	4.67 ± 2.57	5.72 ± 1.94	3.80 ± 3.57	5.19 ± 2.84	6.85 ± 1.64	−1.40 ± 1.39 (.088)	−0.53 ± 0.47 (.110)	**−1.13 ± 0.44 (.004*)**
Total Score	132 ± 37.20	157 ± 23.10	170 ± 16.10	148 ± 26.80	170 ± 17.10	181 ± 10.60	**−16 ± 4.33 (.002*)**	**−13 ± 3.52 (.001*)**	**−10.50 ± 3.34 (.003*)**

*Note: *Note: OSCE checklists score 0–30, except the Relational Skills checklist (−8 to +8). The Total Score is calculated as the sum of all checklist scores. A higher score means a better performance test. A higher score means a better performance test

1st year student N = 221; 2nd Year student N = 133; 3st Year student N = 66

Mean differences is Control Group−Intervention group within year of course between study group, a negative sign indicates better performance in the intervention group

Statistical significance was assessed using the Mann−Whitney *U* test.

*p = <.005 (Mann−Whitney U)

Table 4

OSCE Assessment Results After Clinical Placement by Study Year and Group

Variable	Control Group			Intervention Group			Test of significance[#]		
	Mean ±SD			Mean ±SD			Mean Difference ±SE (p)		
OSCE* Post - internship Simulation	**I Year ±N = 94**	**II Year ±N = 58**	**III Year ±N = 32**	**I Year ±N = 95**	**II Year ±N = 57**	**III Year ±N = 34**	**I Year**	**II Year**	**III Year**
Check List - Bed Bath	24 ± 8.29	26.60 ± 3.44	27.60 ± 1.64	25.80 ± 5.14	27.20 ± 5.31	28.90 ± 1.79	-1.78 ± 1.00 (.164)	-0.65 ± 0.83 (.054)	**-1.29 ± 0.42 (<.001*)**
Check List - Oral Cavity Hygiene	23.80 ± 5.34	25.50 ± 4.56	28.30 ± 2.05	26. 40 ± 3.67	28.00 ± 2.87	29.30 ± 1.52	**-2.6 ± 0.66 (<.001*)**	**-2.53 ± 0.71 (.001*)**	**- 1.01 ± 0.44 (.013*)**
Check List - Perineal Hygiene	24.70 ± 7.39	26.90 ± 3.66	28.90 ± 1.84	26.20 ± 4.73	28.30 ± 2.68	29.60 ± 0.82	-1.51 ± 0.90 (.171)	**-1.44 ± 0.60 (.047*)**	-0.71 ± 0.35 (.082)
Check List - Arterial Pulse Detection	23.40 ± 6.88	27.30 ± 3.85	29.30 ± 1.16	23.40 ± 9.57	28.90 ± 2.19	29.60 ± 1.74	0.015 ± 1.21 (.372)	**-1.65 ± 0.59 (.010*)**	**-0.31 ± 0.37 (.050*)**
Check List - Blood Pressure Measurement	22.90 ± 6.38	26.00 ± 5.51	28.80 ± 1.73	23.90 ± 8.09	27.10 ± 5.39	29.40 ± 1.12	**-0.96 ± 1.10 (.043*)**	**-1.18 ± 1.02 (.039)***	-0.54 ± 0.36 (.198)
Check List - Breath Detection	20.20 ± 9.31	25.20 ± 5.12	28.70 ± 1.91	22.90 ± 7.58	27.70 ± 3.70	29.70 ± 0.68	**-2.77 ± 1.23 (.028*)**	**-2.45 ± 0.83 (.004*)**	**-1.05 ± 0.35 (.025)**
Check List - Relational Skills assessment	3.81 ± 3.46	5.43 ± 2.89	6.03 ± 2.17	5.02 ± 3.11	5.88 ± 2.78	6.83 ± 2.14	**-1.21 ± 0.48 (.008*)**	-0.45 ± 0.53 (.333)	**-0.80 ± 0.52 (.024*)**
Total Score	142 ± 34.10	163 ± 20.55	177 ± 9.20	154 ± 28.73	173 ± 19.01	183 ± 7.11	**-11.53 ± 4.59 (.012*)**	**-10.35 ± 3.69 (.003*)**	**-5.77 ± 2.02 (.003*)**

*Note: OSCE checklists score 0–30, except the Relational Skills checklist (−8 to +8). The Total Score is calculated as the sum of all checklist scores. A higher score means a better performance test

1st year: N = 189; 2nd Year: N = 115; 3rd Year: N = 66

Mean differences is Control Group-Intervention group within year of course between study group, a negative sign indicates better performance in the intervention group

Statistical significance was assessed using the Mann-Whitney *U* test.

* P = <.005 (Mann-Whitney U)

Data availability

The collected data will be stored in a dedicated protected folder on a NAS (Network-Attached Storage) hard drive, equipped with dual redundant backup, without external network access, and with restricted access to the Nursing Science section (Prof. A.Bagnasco, Prof. M.Zanini, Prof. G. Catania, Dr. M. Di Nitto). This hard drive is housed in a server tower located in room I.018 of the DISSAL building (Via A.Pastore, 1 16132 Genoa).

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