

Effect of a Psychologically Safe Simulation and Debriefing Intervention on Clinical Decision-Making Self-Efficacy and Clinical Judgment among Nursing Interns Protocol for a Cluster-Randomized Controlled Trial

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Abstract

Background: Using simulations as the platform of education for nursing interns, those interns become capable of recognizing and managing clinical deterioration. The post-experience discussion contributes hugely to value Students who fear embarrassment, judgment of punishment, or harm to their professional credibility will hide their uncertainty and participate defensively to limit the reflective processes through which clinical reasoning develops.

Objective: This study aims to determine if a standardized psychologically safe simulation and debriefing intervention improves clinical decision-making self-efficacy and observer-rated clinical judgment of the nursing intern. It will also examine whether psychological safety and active reflective engagement account for such improvements.

Methods: A two-arm, assessor-blinded, cluster-randomized controlled trial with approximately 240 final-year nursing interns, from a university-based nursing program in Jordan. 24 intact simulation groups were created, with an average of 10 participants per group. Groups were randomized 1:1 to the intervention or active-comparison condition. The same realistic simulation will be carried out by both groups. The planned actions incorporated a standardized safe-container prebriefing, a non-punitive language of the facilitator, advocacy-inquiry, balanced participation, error normalization with clinical standards specification and structured reflective synthesis. The comparison group received the usual care debriefing of equivalent duration.

Results: The main outcome was clinical decision-making self-efficacy, which was measured at baseline, post-debrief, and 6 weeks. Perceived psychological safety, anxiety, active reflective engagement and observer-rated clinical judgement were secondary outcomes. Estimates of group-by-time effects was fitted using linear mixed-effects models taking into account repeated observations and clustering. Secondary analyses examined calibration of confidence and performance, multilevel mediation, and facilitator competence moderation.

Conclusion: The research evaluated whether psychological safety functions as an educational mechanism rather than as a more general indicator of student satisfaction. Combining self-efficacy with unbiased evaluation of clinical judgment addressed the issue of patient-safety whereby confidence increases but competence does not. Results may inform debriefing standards, faculty development, and transition-to-practice education.

Keywords: Clinical Decision-Making; Clinical Judgment; Debriefing; Nursing Interns; Psychological Safety; Simulation-Based Education; Self-Efficacy

Introduction

Graduates nurses need to recognize deterioration, manage competing problems, voice concerns, initiate appropriate interventions and evaluate responses in uncertain, time pressured situations [1]. These activities call for more than facts. The clinical judgment, self-efficacy, capacity to act, escalate care and seek assistance of staff [2]. The period of transition from student to registered nurse is one of educational and patient-safety significance, particularly when clinical placements offer low or unequal exposure to high-risk or low-frequency events [3].

Simulation-based education closes this gap in experience through standardized exposure to complex events, deliberate practice, and enabling the student to connect assessment findings to nursing actions [4]. Use of evidence syntheses has been shown in research to increase knowledge, skills, perceived competence, self-efficacy and decision making ability [5]. There were variations for fidelity, scenario design, dose, learner readiness and comparator condition [4-9]. Simulation isn't Educationally Self-Executing. The scenario experienced needs a debrief so it can be reflected upon, interpreted and formulated into knowledge that will inform future practice [10-12].

Debriefing is a learning conversation that allows pupils to construct a narrative about an event, make their thinking visible, compare intentions and outcomes and consider alternatives. There are multiple ways to debrief learners including advocacy-inquiry, plus-delta, gather-analyze-summarize, PEARLS, and debrief for meaningful learning which can be effective where they match the learners, learning objectives, and learning context [10,12-14]. Across approaches, the element of meaningful learning is learners engaging truthfully rather than providing replies they think faculty want [15-17]. Psychological safety is particularly relevant to this last point because it supports active and honest participation and reduces fear or defensiveness during debriefing [14].

Being straightforward entails risk in human relations [18,19]. Nursing interns might have to identify that they missed a cue, delayed escalation, misinterpreted data, or chose an unsafe priority. It may also become necessary for them to inquire of their peers or display uncertainty before faculty and classmates [15,17,20]. Psychological safety is a belief that speaking up, asking for help, and discussing mistakes won't be met with humiliation, punitive judgment, or damage to a person's relational status [18,19]. Psychological safety does not entail lowering standards, boarding negative feedback, or dodging accountability [21]. It allows for tough feedback and critique of performance without violation of the learner's dignity or professional identity [15,17,22].

Studies in nursing simulation have found faculty member behavior, peer relationships, observation, expectations, time pressure, and tone of feedback to be determinants of psychological safety [23-25]. These studies specifically identify facilitator behavior, expectations, observation, feedback/debriefing, and relationships with faculty and peers as important features of psychological safety in nursing simulation. Instruments for measurement of learner's perceived exposure; uncertainty; lack of support; and inter-personal risk have also been developed specific to simulation [26]. Park and Kim's 14-item scale contains four corresponding dimensions: dealing with uncertainty, being exposed, being unsupported, and interpersonal risk. However, a lot of literature is still descriptive, qualitative, or cross-sectional [25,27]. Not many studies have tested whether deliberately strengthening psychological safety alters reflective engagement, clinical judgment, or task-specific self-efficacy [27]. The nursing-simulation literature review by Daniels, *et al.* identified only 13 eligible articles, illustrating the relatively limited evidence base on psychological safety in this setting.

Another limitation is the tendency for educators to privilege confidence over any other outcome [28]. Confidence can aid in communication, perseverance, and taking timely action [2,29]. However, it is not the same as effectiveness [28]. An incorrect confidence level in actual performance may pose a risk in clinical deterioration [28,29]. The current study thus conceives the outcome as clinical decision-making self-efficacy: this is your belief, specific to a task, about your capability, for identifying and utilizing relevant information to choose and communicate an intervention and evaluate the outcome [30,31]. Observer-rated clinical judgment will be measured in parallel so that changes in perceived capability can be interpreted alongside performance [32-34].

The distinction between confidence and observed performance is particularly well supported by Liaw, *et al.* [28], who specifically compared self-reported confidence with observed clinical performance in nursing simulation. O'Neill, *et al.* [29] also identified both overconfidence and lack of confidence among factors influencing escalation of care for deteriorating patients. The LCJR is well established for observer-based assessment of clinical judgment in simulated nursing care.

This protocol outlines a randomized controlled trial for a standardized simulation and debriefing intervention. The main contribution of this project is mechanistic in nature. It will test whether the intervention increases learners' perceived psychological safety, whether safety supports active reflective engagement and whether reflective engagement contributes to clinical reasoning and self-efficacy.

Theoretical and conceptual framework

Psychological safety as the learning climate

The psychological safety theory by Edmondson gives a perspective on learners withholding their questions and concerns and mistakes that would be situational disclosure that would enhance learning [18,19]. Perceptions of interpersonal risk are made in the presence of the faculty, peer observers [24,26]. The intervention evaluated in this study targets clear expectations, inclusive leadership, respectful challenge, no blame response, recognition of uncertainty, and separation of the person from the performance [15,17,18]. Instead of facilitator intention, learner-perceived safety is the theoretically relevant construct [24,26].

Experiential learning as the learning process

Kolb's [35] experiential learning theory proposes that learning is a four-step process that takes place in stages. The simulation will supply the concrete experience [36]. Debriefing offers a systematic way to reflect on decisions, pinpoint differences, build better explanations and plan future action [10,11,22]. The use of psychological safety is thought to enable these processes by mitigating defensive impression management and increasing inclination to expose reasoning to examination [17,18,37].

Self-efficacy as the motivational outcome

According to Bandura's Self-Efficacy Theory, performances are interpreted by people and that determines their beliefs about future capability [30]. Experiencing mastery is very powerful, but influence is affected by how learners interpret difficulties, feedback, emotional arousal, and improvement [30,31]. Bandura's framework identifies mastery experiences, vicarious experiences, verbal persuasion, and physiological/affective states as major sources from which efficacy beliefs are formed. An insightful debriefing that is concurrently medically safe and rigorously safe could allow students to interpret an imperfect performance as evidence that reasoning can be upgraded rather than as proof of fixed inadequacy [16,17,22]. Psychological safety in simulation is associated with more active and honest participation, while structured debriefing can improve self-efficacy and clinical reasoning outcomes. This interpretation may enhance one's willingness to act, communicate and seek help in future clinical situations [16,38]. Roussin, *et al.* [16] specifically examined the relationship among psychological safety, self-efficacy, and speaking-up behavior in healthcare simulation.

Integrated proposition

The impact of the psychological safety intervention is to improve perceived psychological safety, which allows for active reflective engagement. This reflective engagement strengthens clinical reasoning and clinical judgement. Improved clinical reasoning ultimately leads to clinical decision-making self-efficacy. Competence of the facilitator expected to strengthen the relationship between psychological safety and reflective engagement. A straight path between psychological safety and self-calibration of efficacy will also be estimated, since reducing threat through constructive feedback can influence efficacy before measurable performance change occurs (Figure 1).

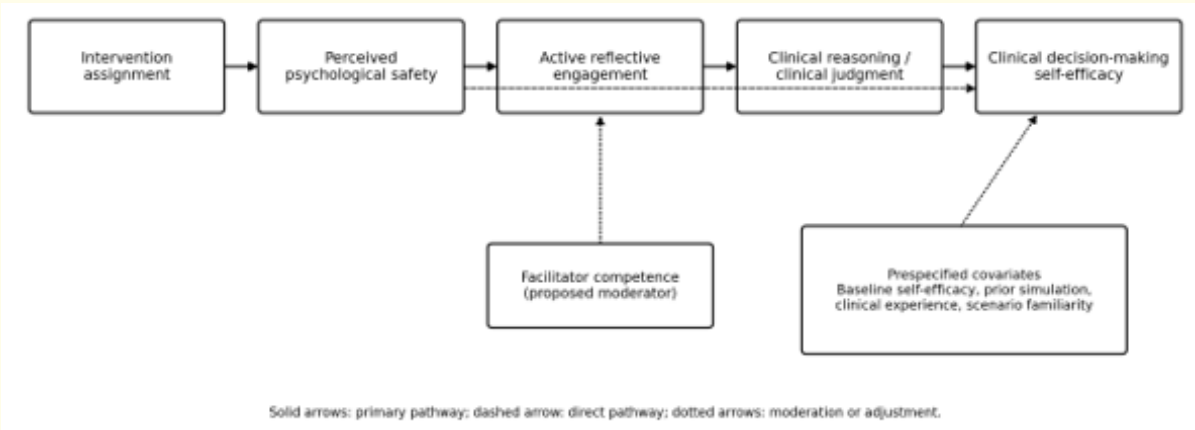


Figure 1: Integrated conceptual model linking the intervention to clinical decision-making self-efficacy.

Note: The cause of exposure is the intervention. The crucial variables that will be introduced are psychological safety. Clinical judgment serves as a secondary outcome objective and as a potential explanation. Because psychological safety and engagement are assessed in the same debriefing period, the serial indirect pathway will be interpreted cautiously.

Study Objectives and Hypotheses

Primary objective

The aim of this study was to assess if the intervention comprising of psychologically safe simulation and debriefing would create a greater improvement in clinical decision-making self-efficacy than the usual structured debriefing, immediately post-intervention period and at six-week follow-up.

Secondary objectives

- 1. To compare intervention and comparison groups on perceived psychological safety, active reflective engagement, anxiety, and observer-rated clinical judgment.
- 2. To evaluate whether changes in self-efficacy accompany changes in observer-rated clinical judgment.
- 3. To study perceived psychological safety and active reflective engagement as potential mechanisms of the intervention effect.
- 4. To investigate whether facilitator competence enhances psychological safety’s role in predictive reflective engagement.

Hypotheses

- H1: The intervention group will display a larger increase in clinical decision-making self-efficacy at baseline, immediately post-intervention, and follow-up than the comparison group.
- H2: Compared to the active-comparison group, the intervention group is expected to report higher perceived psychological safety and greater active reflective engagement.
- H3: The clinical judgement of the intervention group will be rated as greater than the comparator group.

- H4: Psychological safety, along with meaningful engagement in active reflection, will enhance the indirect association of intervention assignment and follow-up self-efficacy.
- H5: When facilitators are more competent, the relationship between psychological safety and active reflective engagement will strengthen.

Methods and Results

Study design

A assessor-blinded cluster-randomized trial with repeated measures, two-arm parallel-group was conducted. To limit contamination from peer remarks or facilitator behavior, intact internship or simulation groups will be the unit of randomization. Participants will be tested for the baseline stage (T0), right after debriefing (T1), and 6 weeks after it (T2). The first analysis was by the intention to treat. The template for intervention description and replication will guide the description of the intervention, while the final trial report followed guidance for cluster-randomized trials [39].

Setting

The nursing simulation center located within a university in Jordan will conduct the study. The center has a monitoring and emergency equipment which is standardized, audiovisual recording is possible, high-fidelity adult simulator is available and it has a separate room for debriefing. The nursing program has a final internship or transition-to-practice period in which students are expected to synthesize assessment, prioritization, communication, intervention and evaluation. Recruitment can continue through the internship blocks until the pre-specified number of clusters is achieved.

Participants

The target population will be final-year baccalaureate nursing interns completing the programme's transition-to-practice component.

Inclusion criteria

- Enrollment in the final internship or transition to practice.
- Fulfillment of necessary adult health and acute care course requirements.
- Having participated in at least one previous simulation activity so that basic equipment orientation does not dominate the intervention.
- Can read the study language and provide written informed consent.

Exclusion criteria

- The candidate must have an educational background that is comparable to that of a registered nurse.
- Formal Certification as a Simulation instructor or Healthcare Debriefing.
- Participation in developing, translating, or pilot testing of the intervention or measures.
- Missing from the assigned scene or debriefing session.

Sample size

The sample size is 240 targets in 24 intact simulation groups; approximately 10 participants per cluster and 12 clusters per study arm. The estimate used in the calculation is based conservatively on a standardized between-group effect of 0.45 for the primary self-efficacy outcome, two-sided $\alpha = .05$, and 80% power, requiring approximately 79 participants per arm under individual allocation. A design effect of 1.27 for average cluster size of 10 and an intra-class correlation of .03 increases the requirement to be of the order of 100 participants

per arm. To achieve the target sample size of 240, each study arm will need to recruit 120 participants. This number accounts for a potential dropout rate of 15%. Since the primary mixed model will incorporate repeated measurements and baseline adjustment, this number is conservative. Secondary mechanistic mediation and moderation analysis will be interpreted according to their precision and not based on statistical significance.

Recruitment and informed consent

Interns who are deemed eligible will receive written and verbal information regarding the study from a researcher who is not responsible for the academic grading of the subject. Participant recruitment took place before randomization outcome disclosure. Participation in the research measures and use of recorded data is voluntary and will not affect academic evaluation, the ability to participate in clinical placement or access to educational activities. The participants are advised that the simulation session may form part of the curriculum, whereas use of the questionnaire and video for research requires separate consent depending on institutional policy.

Cluster randomization and allocation concealment

After the baseline enrollment of each internship block, intact simulation groups should be randomized 1:1 to the intervention or active-comparison condition. A statistician or administrator who is independent of recruitment, facilitation or outcome assessment will generate the allocation sequence using randomly permuted blocks of variable size. The allocation will be hidden in opaque, sealed envelopes with successive numbers or an equivalent secure electronic system, until the group's turn. If the inclusion of multiple internship blocks is allowed, stratified randomization by block will be used to maintain balance over time.

Blinding

Participants and facilitators will know the debriefing process. Assessors of the baseline and follow-up simulation performance will be, when possible, blinded to intervention assignment and assessment occasion. The video files will be renamed and shown randomly. Statistical analysts will get coded groups names. The framing of the questions should not give away the identity of the respondent.

Standardized simulation scenario

Both groups will undergo the identical standardized adult deterioration scenario. This case describes a hospitalized adult with progressive respiratory and circulatory compromise requiring focused assessment, trend interpretation and prioritizing, organized escalation, immediate nursing intervention and reassessment. All scenarios will contain identical objective, cues, set-up timing, equipment, confederate behavior and expected actions. Experts in simulation and acute care nursing will review the scenario for content validity and it will be piloted with non-participating learners. At follow-up, a scenario of similar complexity will reduce recall while maintaining similar demands on clinical reasoning in parallel.

Intervention condition

The package will comprise a standardized psychologically safe simulation and debriefing package informed by simulation best-practice standards, the safe-container approach and debriefing models that explicitly address psychological safety [15,17,40,41]. To clarify the purpose and roles of the safe-container as well as confidentiality limits, simulator limitations and expectations for participation with respect, people are given this brief prebriefing. Following the experience, a 30–40-minute debriefing will take place. This will be a facilitated discussion in the sequence of reaction, analysis, and synthesis. This intervention aims for a reduction of interpersonal threat without reducing clinical challenge or accountability. Table 1 lists the components needed and their proposed mechanisms.

Component	Standardized facilitator behavior	Intended mechanism
Safe-container prebriefing	Clarify objectives, roles, confidentiality limits, simulator limitations, evaluation status, and the expectation that capable learners may make errors in unfamiliar situations.	Reduces uncertainty and evaluation threat.
Basic assumption	State that participants are capable, intelligent, and trying to improve; separate the learner's identity from the observed performance.	Protects dignity while preserving accountability.
Reaction and emotional regulation	Invite a brief reaction, acknowledge stress, and transition deliberately from emotion to analysis.	Supports readiness for reflective processing.
Advocacy-inquiry	Describe an observed action and its consequence, state the facilitator's concern, and invite the learner to explain the frame guiding the action.	Makes reasoning visible without accusation.
Balanced participation	Use inclusive prompts, limit domination, and invite quieter members without coercive public exposure.	Supports voice and equitable reflection.
Error normalization with standards	Treat errors as analyzable learning data while explicitly discussing safe nursing standards, escalation thresholds, and professional limits.	Combines safety with clinical rigor.
Reflective synthesis	Identify missed cues, alternative priorities, and one specific action to transfer to future practice.	Supports conceptualization and active experimentation.
Closure and repair	Summarize strengths and improvement priorities, address any safety breach, and provide support resources if distress persists.	Consolidates mastery interpretation and restores trust.

Table 1: Required components of the psychologically safe simulation and debriefing intervention.

Active-comparison condition

Those in the active-comparison group will receive the institution's standard structured debriefing for the same scenario for the same duration. The comparison manual has review of objectives, participant reactions, discussion of performance, corrective feedback, and summary. The intervention-specific safe-container script won't be needed, nor the explicit basic-assumption statement, standardized error-normalizing sequence, balanced-participation prompts, or prescribed advocacy-inquiry format. The comparison condition will be respectful and ethically acceptable; it will not be intentionally punishing or psychologically unsafe. We will assess treatment differentiation using an independent checklist.

Facilitator preparation and fidelity

Facilitators will undergo a standardized workshop in which they will learn about psychological safety, the manuals for both the intervention and comparison, advocacy-inquiry, management of emotional responses, recognition and repair of safety breaches, and use of the fidelity checklist. They will practice on pilot groups and must reach a threshold of specified competence prior to the study sessions. We will counteract the varying facilitator effects by balancing facilitators across conditions. Independent review will apply to recordings of minimum 25% of sessions in each condition. Indicators of fidelity will include provision of relevant components, session duration, learner speaking time, use of inquiry, differentiation of treatment, and absence of humiliating or punitive language. Debriefing competence will be rated using the Debriefing Assessment for Simulation in Healthcare (DASH; [42]).

Outcomes and measurement instruments

Table 2 lists the study constructs, operational definitions, measures and evaluation points. Before use, permissions and licensing requirements will be confirmed. When the Arabic version can't be validated, the translation and cultural adaptation will follow forward

translation, a synthesis, back translation, expert review, cognitive interview, and pilot test. When relevant factors, to be examined in the study sample will evaluate its internal consistency.

Construct	Role	Operational definition	Measure	Timing
Clinical decision-making self-efficacy	Primary outcome	Belief in capability to gather information, use resources, identify problems, implement decisions, communicate, and evaluate outcomes.	NASC-CDM self-confidence subscale	T0, T1, T2
Psychological safety	Process outcome / mediator	Perceived freedom to disclose uncertainty, question decisions, and discuss errors without humiliation or punitive judgment.	Psychological Safety in High-Fidelity Simulation Scale	T1
Active reflective engagement	Process outcome / mediator	Disclosure of reasoning, critical self-assessment, feedback use, consideration of alternatives, and formulation of future strategies.	Behavioral coding plus brief self-report items	During debriefing and T1
Clinical judgment	Secondary outcome / proposed mechanism	Quality of noticing, interpreting, responding, and reflecting during a standardized scenario.	Lasater Clinical Judgment Rubric	T0 and T2
Decision-making anxiety	Secondary outcome	Anxiety experienced when gathering information, identifying problems, and selecting or evaluating clinical actions.	NASC-CDM anxiety subscale	T0, T1, T2
Facilitator competence	Fidelity indicator / moderator	Quality of structure, inquiry, learner engagement, and support for future performance.	DASH rater form	Recorded sample

Table 2: Study outcomes, measures, and assessment points.

Note: DASH = Debriefing Assessment for Simulation in Healthcare; NASC-CDM = Nursing Anxiety and Self-Confidence with Clinical Decision Making; T0 = Baseline; T1 = Immediate Post-Intervention; T2 = Six-Week Follow-Up.

Clinical decision-making self-efficacy

The primary outcome will be measured through the self-confidence subscale of the Nursing Anxiety and Self-Confidence with Clinical Decision Making scale [43]. The scale evaluates the degree of confidence in using resources, gathering information, identifying problems, implementing and evaluating decisions. What is more, it is more specific than the global confidence rating and has been cross-culturally validated with recent Spanish validation [44]. The entire instrument is going to be administered, so anxiety will be examined as a secondary outcome.

Psychological safety

The Psychological Safety in High-Fidelity Simulation Scale was developed for nursing students and examines things such as uncertainty, exposure, lack of support, and interpersonal risk [26]. The scale will serve to check and measure manipulation of processes. Since the intervention starts in prebriefing and continues through the debriefing, the post-session score reflects the learner's full experience of the intervention period.

Citation: Ahed J Alkhatib, *et al.* "Effect of a Psychologically Safe Simulation and Debriefing Intervention on Clinical Decision-Making Self-Efficacy and Clinical Judgment among Nursing Interns Protocol for a Cluster-Randomized Controlled Trial". *EC Gynaecology* 15.10 (2026): 01-16.

Clinical judgment

The Lasater Clinical Judgment Rubric will measure noticing, interpreting, responding, and reflecting in the baseline and follow-up scenarios [32,45]. Two independent evaluation of recorded performances will be done by raters. To use sample videos, raters will carry out calibration exercises. Before formal scoring, we will estimate interrater reliability and monitor it throughout the study [33].

Active reflective engagement

The primary assessment will measure behavioral coding of recorded debriefings reflecting incidence. A theoretical coding guide will refer to the rating of the disclosure of reasoning, the discussion of errors, questioning, the consideration of alternatives, the uptake of feedback, and the formulation of transferable future actions. A prespecified proportion of sessions will independently be rated by two trained coders, and agreement will be assessed using intraclass correlation coefficients or weighted kappa, as appropriate to level of coding. A brief self-report measure will add triangulation but will not be viewed as a fully validated latent scale unless psychometric results support such an interpretation.

Participant and contextual variables

The baseline variables will include age, sex, academic mean or GPA, past work in healthcare, number of previous simulation sessions, exposure to clinical issue, recent acute-care placement, familiarity with scenario and baseline self-efficacy. Covariates will be prespecified and confined to variables with a well-established theoretical or precision-enhancing role. The primary total-effect model will not adjust the post-randomization variables.

Data collection procedure

At time point T0, all participants will complete (a) demographics measures, and the NASC-CDM, and (b) a standardized baseline scenario or equivalent clinical judgement assessment. The assigned simulation and debriefing condition will be completed by study clusters. Participants will assess the psychological safety, reflective engagement, debriefing experience, and NASC-CDM measures right after debriefing. T2 participants will be required to complete a parallel simulation scenario rated with the Lasater Clinical Judgment Rubric before completing the NASC-CDM. The follow-up self-efficacy measure will be administered after the scenario to permit mechanistic analysis to examine whether better reasoning leads to better efficacy beliefs. Nonetheless, the overall impact of the intervention effect will be estimated in all three self-efficacy assessments.

Study activity	Enrollment	T0 baseline	T1 immediate	T2 six weeks
Eligibility screening	X			
Written informed consent	X			
Demographic and contextual variables		X		
NASC-CDM self-efficacy and anxiety		X	X	X
Baseline clinical judgment scenario		X		
Randomized simulation and debriefing intervention			X	
Psychological safety			X	
Active reflective engagement coding			X	
Parallel clinical judgment scenario				X
Adverse-event and fidelity monitoring			X	X

Table 3: Schedule of enrollment, intervention, and assessments.

Note: NASC-CDM = Nursing Anxiety and Self-Confidence with Clinical Decision Making.

Data management and quality assurance

Participants will each receive a unique ID. Data from the questionnaires, outcome ratings, and participant-identification linkage file will be stored separately on encrypted institutional systems with role-based access. There will be prespecified scoring rules, range checks, duplicate verification of key variables, and an auditable log of the data-cleaning process. The video files will get encrypted, separated from the other stored evidence, and deleted on an approved retention schedule. The statistical analysis plan alongside coding manuals will be completed before group codes are released to the chief analyst.

Statistical analysis

We will conduct our analysis using a validated statistical package such as R, Stata, SPSS, or Mplus. Two-sided tests will use $\alpha = .05$, but interpretation will focus on effect size and 95% confidence intervals. The baseline characteristics will be summarized by study arm, without significance testing through p-values as an indicator of successful randomization. The measures of more than one item will be evaluated for reliability using coefficient omega. It also uses Cronbach's alpha. We will report interrater reliability using confidence intervals for the Lasater rubric, DASH, and behavioral coding.

Primary analysis

The analysis of the primary outcome will utilize a linear mixed-effects model with study group, time, and their interaction as fixed effects. The model will incorporate random intercepts for participants and random clusters, and a facilitator will be included as an additional random or fixed effect, depending on the number and distribution of facilitators. Inclusion of baseline self-efficacy and stratification variables to improve precision. The main estimates will be mean differences between groups at T1 and T2, with 95% confidence intervals, and the overall group-by-time test. Standardized effects will also be expressed.

Secondary outcomes

Clinical judgment will be analyzed through either a mixed model or CNSQ analysis comparing T2 scores, adjusting these for baseline clinical judgment, cluster, facilitator and pre-specified covariates. Using multilevel models that include cluster membership as a covariate, we will compare the groups on psychological safety and active reflective engagement. The analysis of anxiety will follow a repeated-measures approach, identical to that of self-efficacy. Residual diagnostics will assess distributional assumptions; robust standard errors or generalized mixed models will be utilized as warranted.

Mechanism and moderation analyses

The prespecified mechanistic analyses will apply a multilevel path analysis or other structural equation modeling framework to estimate intervention assignment to follow-up self-efficacy associations through psychological safety, active reflective engagement, and follow-up clinical judgment. Indirect effects will be estimated using Bootstrap or Monte Carlo confidence intervals. This is a serial ordering of psychological safety and engagement. Given that psychological safety and engagement are evaluated during the same debriefing time, it will be seen as theory consistent but not definitively causal. We will explore how programming can impact the base pay of selected workers. Moderated mediation will only be considered if the initial interaction is precise enough and the effective sample size supports model complexity.

Confidence-performance calibration

The calibrations will be explored by examining the correlation between the standardized self-efficacy and clinical judgment scores, and estimating regression models predicting follow-up clinical judgment from self-efficacy, study group, baseline scores, and other relevant covariates. The technique of using standardized difference scores can be used descriptive to identify disproportionate confidence gains. The findings will not be taken as diagnostic labels of individual learners; rather, they are secondary analyses.

Missing data and sensitivity analyses

Missing data will be described by study arm in terms of amount, pattern and reason. Mixed effects models will provide valid estimators assuming that missing data is MAR. If suitable, the use of multiple imputation for missing covariates and outcomes will be considered, with the cluster and longitudinal structured incorporated into the imputation model. We will conduct sensitivity analyses using fidelity thresholds to create per-protocol models, excluding participants with major protocol deviations, and using different covariance structures. Inference will not depend only on complete-case analysis (Table 4).

Objective	Variables	Primary analysis	Key estimate
Intervention effect on self-efficacy	NASC-CDM at T0, T1, and T2	Linear mixed-effects model	Group $\times$ time effect and adjusted mean differences
Intervention effect on clinical judgment	LCJR at T0 and T2	Mixed model or ANCOVA	Adjusted T2 mean difference
Intervention effect on psychological safety and engagement	Safety and engagement scores	Multilevel regression	Adjusted group difference
Mechanistic pathway	Assignment, safety, engagement, LCJR, self-efficacy	Multilevel path analysis	Specific and total indirect effects
Facilitator moderation	DASH $\times$ safety interaction	Multilevel interaction model	Interaction and conditional effects
Confidence-performance calibration	NASC-CDM and LCJR	Correlation and adjusted regression	Association and standardized discrepancy

Table 4: Prespecified analyses according to the study objectives.

Note: ANCOVA = Analysis of Covariance; DASH = Debriefing Assessment for Simulation in Healthcare; LCJR = Lasater Clinical Judgment Rubric; NASC-CDM = Nursing Anxiety and Self-Confidence with Clinical Decision Making.

Ethical considerations

The responsible institutional review board will be obtained approval prior to recruitment. When students are participating it is voluntary and will not affect their grades, clinical placement or educational resources.

A scholar who is not dependent on academic marking will seek consent. The consent form will specifically refer to audiovisual recording as simulation performance and debriefing can contain identifiable behavior and emotionally-sensitive discussion.

Participants may feel embarrassed or distressed in relation to their errors or clinical judgment. Trainers will be instructed to detect signs of distress, halt debriefing as needed, provide private follow-up, and refer students to student-support services. Psychological safety will not provide a shield to protect unsafe practice debate. Feedback will stay behavior-specific, evidence-based, respectful and proportionate. The institution will address serious concerns regarding patient or learner safety according to policy.

All participants will set expectations around confidentiality but other participants cannot be controlled to not share a group simulation. Aggregate data and de-identified quotes will be used for publications. Incidents where due to study procedures privacy will be breached causing severe distress or conflict will be recorded as adverse events. These will be reviewed by study leadership and ethics committee.

Dissemination and knowledge translation

This research will be published in a peer-reviewed publication and presented at a relevant conference. We will also provide feedback to our students, faculty, and the leadership of the Ottawa Simulation Centre. Reporting will contain the intervention manual, indicators of fidelity, effect size estimates with confidence intervals and context sufficient to allow replication. De-identified code and data dictionary as well as aggregate data will be made available through institutional or public repository, subject to ethics approval and participant permission. Findings will also inform a faculty-development module on debriefing that is clinically rigorous but psychologically safe.

Discussion

This protocol tests whether psychological safety acts as an educational mechanism during simulation rather than just a general measure of satisfaction. The intervention aims to establish an adequate level of interpersonal security for learners to communicate uncertainty, justify reasoning, receive corrective feedback and inquire about errors without humiliation. The goal isn't comfort as an alternative to performance but a reflective approach that facilitates safer clinical decision-making.

The study has many methodological strengths. Contamination of learners training together is minimized. A comparison that is active controls scenario exposure, debriefing time, and facilitator attention. Manuals and treatment checks differ from usual debriefing to avoid contamination of the intervention. In blindness of the study, the clinical judgment prevents the study from equating confidence with competence. Instead of making assumptions, we measure fidelity and the competence of facilitators. Additionally, the statistical model we create accounts for several things: a repeated observations design, a clustered intact-group allocation design, and a facilitator effects design.

The ability to have confidence and perform well differs in meaning [28,46]. As a result, calibrated confidence would be underpinned by stronger reasoning rather than weaker reasoning [46]. Increased judgment without increased self-efficacy might indicate that interns developed knowledge but remain hesitant to trust themselves [30]. If self-efficacy enhancement was not accompanied by improved clinical judgment, we would be concerned about overconfidence and we would argue for more feedback on performance and more practice [28,30,46]. If we see no results, we will need to look at manipulation and fidelity findings too [47]. This would distinguish whether the failure is due to intervention or failure of the theory itself [47].

The analysis of mechanics is secondary on purpose [47,48]. The integrated model posits psychological safety, reflective engagement, clinical reasoning, and self-efficacy in sequence. However, safety and engagement are actually co-created in the same debriefing [17]. You cannot reach an absolute conclusion of causation from their statistical ordering [48-50]. Behavioral coding, objective follow-up performance, and explicit temporal limitations will nonetheless provide a stronger test than cross-sectional self-report only [48,49,51].

Some restrictions will be expected. The study will be conducted in one educational program which threatens the generalizability of curricula, languages, and contexts. Participants and facilitators cannot be blinded. The side-by-side intervention may contain naturally occurring affirmative testimonies that lessen the treatment contrast, while separate scripts may introduce allegiance to the facilitator effects. The reflective-engagement coding system requires testing out on actual samples and doesn't capture all dimensions of internal reflection. A follow up after six weeks evaluates short term retention not transition to independent clinical practice. Eventually, simulation performance is system-specific and cannot fully reflect patient's outcome.

This evaluation however may have implications for nursing education in practice. If psychological safety competencies are effective, they should be viewed as essential for debriefer preparation, not an optional style of interaction.

Simulation programs should monitor psychological safety and quality of debriefing along with objective performance and satisfaction. The model could also apply to clinical transition programs, in which new graduate nurses may require teams that allow questioning, escalation and uncertainty disclosures, while maintaining clear professional boundaries.

Conclusion

This trial will assess an innovative intervention designed to promote psychological safety in nursing interns. The interpersonal climate that allows for candor is explained by Edmondson's theory, the transformation through reflection is explained by Kolb's theory, and the interpreted mastery that develops task-specific self-efficacy is explained by Bandura's theory. In the study, we will use an active comparison, a fidelity monitoring measure, some behavioral process measures, as well as a blinded clinical judgment assessment to test whether psychological safety underpins reflective learning and calibrated confidence. The findings might help develop simulations, teachings for faculty, and transition to practice education while ensuring safety in clinical decision-making.

Ethics Approval and Consent to Participate

Ethics approval will be obtained before recruitment. Written informed consent will be obtained from all participants.

Consent for Publication

Not applicable. No identifiable participant information is included in this protocol.

Availability of Data and Materials

No participant data have yet been generated. The final study will share de-identified materials and analytic code to the extent permitted by consent, ethics approval, and institutional policy.

Competing Interests

The authors declare no competing interests.

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