FULL STUDY PROTOCOL, STATISTICAL ANALYSIS PLAN (SAP) & INFORMED CONSENT FORM (ICF)

Official Title: Effect of AI-Assisted Rule-Based Adaptive Simulation on Physiology Learning Outcomes Among Health Science Students: A Randomized Controlled Trial

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1. Personnel

Role	Name/Institution
Principal Investigator	Dr. Jeevarathinam Thirumalai
Study Institution	Saveetha Institute of Basic Medical Sciences (SIMATS), Chennai, India
Ethics Board	Institutional Scientific Review Board, SIMATS

2. Introduction

2.1 Background & Aims

Healthcare professionals are required to integrate foundational physiological knowledge with clinical reasoning to ensure safe and effective patient care. A persistent challenge in health sciences education is the gap between students' ability to recall physiological concepts and their capacity to apply this knowledge meaningfully in clinical decision-making contexts. This theory-practice disconnect has been consistently reported across nursing and allied health education and is associated with reduced clinical preparedness and learner confidence.

Traditional preclinical physiology education commonly relies on curriculum-based instructional approaches centered on didactic teaching, textbook-directed learning, tutorials, and laboratory practical activities. Although such approaches may facilitate short-term knowledge acquisition, they are often insufficient for promoting higher-order cognitive processes, including interpretation, integration, and application of physiological principles in clinical contexts. Consequently, students may demonstrate adequate theoretical understanding yet experience difficulty explaining physiological mechanisms underlying patient presentations or justifying clinical decisions.

Aims of this study:

- To evaluate the effectiveness of AI-assisted algorithm-supported adaptive screen-based simulation compared with conventional physiology instruction on physiological knowledge acquisition and reasoning ability among undergraduate health science students.
- To assess the impact of the intervention on secondary outcomes including conceptual understanding, learning engagement, cognitive load, and academic self-efficacy at post-intervention and four-week follow-up.

2.2 Background Literature Review

Simulation-based education has emerged as an effective pedagogical approach to bridge the gap between theoretical knowledge and clinical application by enabling experiential, learner-centered engagement in realistic clinical scenarios. Among available simulation modalities, screen-based simulation offers particular advantages for physiology education, as physiological processes are inherently dynamic and often not directly observable during routine clinical encounters.

Recent advances in adaptive educational technologies have expanded the capabilities of simulation-based learning. Rule-based adaptive simulation systems can dynamically adjust case complexity, sequence learning activities, and provide automated formative feedback according to learner performance. These adaptive features support individualized learning pathways and are aligned with established educational theories including experiential learning, cognitive load management, and self-efficacy development.

Despite increasing interest in AI-assisted educational technologies, robust empirical evidence evaluating their effectiveness in foundational science education, particularly physiology, remains limited. Existing studies have largely focused on feasibility, usability, or learner satisfaction rather than objective learning outcomes derived from rigorous experimental designs.

Theoretical Framework: This study is grounded in:

- **Experiential Learning Theory** (Kolb, 2014): Learning through doing and reflection in simulation environments.
- **Cognitive Load Theory** (Sweller, 2020): Managing intrinsic, extraneous, and germane cognitive load to optimize learning.
- **Self-Efficacy Theory** (Bandura, 1977): Mastery experiences in adaptive simulation enhancing learner confidence.

3. Study Protocol

3.1 Research Design Outline

This study was designed as a **prospective, two-arm, parallel-group randomized controlled trial (RCT)** with repeated-measures assessment at three predefined time points:

- **Time 1 (Baseline):** Week 1, prior to intervention commencement
- **Time 2 (Post-Intervention):** Week 13, immediately following the 12-week intervention
- **Time 3 (Follow-up):** Week 17, four weeks post-intervention

The trial was conducted at **Saveetha Institute of Basic Medical Sciences (SIMATS), India**, between **August 2025 and January 2026**.

The study was designed and reported in accordance with the **Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines**. The intervention description additionally followed the **Template for Intervention Description and Replication (TIDieR) checklist** and the **INACSL Healthcare Simulation Standards of Best Practice**.

3.2 Participants

Undergraduate health science students enrolled at Saveetha Institute of Basic Medical Sciences, India, registered for a Human Physiology course during the study period (August 2025 - January 2026) were eligible for participation.

Study Setting: Saveetha Institute of Basic Medical Sciences, SIMATS, Chennai, India.

Programs included: Physiotherapy, Occupational Therapy, Nursing, and Allied Health Sciences.

3.3 Sample Size Determination

Sample size estimation was performed using **G*Power version 3.1.9.7** for repeated-measures analysis of variance (ANOVA) with a within-between interaction.

Parameters assumed:

- Effect size: medium ($f = 0.25$)
- Type I error rate (α): 0.05
- Statistical power: 0.95
- Number of groups: 2
- Measurement occasions: 3
- Correlation among repeated measures: 0.5

Calculated minimum sample: 292 participants per group.

Final target enrollment: 336 participants per group (accounting for an anticipated 15% attrition rate), yielding a **total sample size of 672 participants**.

3.4 Eligibility Criteria

Inclusion Criteria:

- Undergraduate students enrolled in health science programs (Physiotherapy, Occupational Therapy, Nursing, Allied Health Sciences)
- Registered for a Human Physiology course during the study period
- Age between 18 and 25 years
- Proficient in English
- Access to an internet-enabled personal device capable of supporting web-based educational applications

Exclusion Criteria:

- Students with prior formal exposure to structured simulation-based physiology instruction or adaptive digital learning platforms (to minimize potential contamination effects)

3.5 Randomization and Blinding

Randomization: Following completion of baseline assessments, participants were randomly allocated in a 1:1 ratio using a **computer-generated random sequence**, stratified by academic program to ensure balanced group representation.

Allocation Concealment: Maintained through **sequentially numbered, opaque, sealed envelopes** prepared by an independent researcher not involved in recruitment or assessment.

Blinding: Outcome assessors and data analysts were blinded to group allocation throughout the study. Blinding was maintained during the scoring and data analysis processes.

Contamination Control: Participants were instructed not to share intervention materials, simulation access, or case content with peers assigned to the alternate study condition during the study period.

3.6 Intervention: AI-Assisted Algorithm-Supported Adaptive Simulation

Participants assigned to the intervention group received physiology instruction through a **screen-based adaptive simulation learning environment** incorporating AI-assisted educational feedback over a **12-week period**. The simulation-based instruction replaced conventional lecture-based teaching for selected physiology topics during the intervention phase.

Intervention Dosage:

- **Total instructional exposure:** 24 hours across 12 weeks

- **Session format:** 2 hours/week × 12 weeks
- **Case exposure:** Approximately 48-72 simulation cases spanning 8 physiological systems

Simulation Session Structure

Each session comprised three phases:

Phase 1: Pre-Briefing (15 minutes)
Facilitator-led orientation including: introduction to simulation interface, clarification of session objectives, establishment of psychological safety, review of learner expectations, and confirmation of technical readiness.

Phase 2: Individual Simulation Activity (90 minutes)
Participants independently completed multiple physiology-focused clinical case scenarios. Each case followed a structured instructional workflow:

1. **Clinical Scenario Presentation** — Patient scenario with clinical history, simulated vital signs, laboratory findings, and animated visualizations of physiological processes.
2. **Hypothesis Generation** — Participants identified potential physiological explanations for presented clinical findings.
3. **Diagnostic Decision** — Learners selected appropriate diagnostic investigations and interpreted simulated physiological data.
4. **Therapeutic Decision-Making** — Participants selected management strategies and predicted physiological consequences.
5. **Adaptive Feedback** — Automated formative feedback explaining reasoning errors, clarifying physiological mechanisms, and highlighting key learning concepts.
6. **Case Progression** — Subsequent cases adaptively adjusted in complexity according to learner performance.

Approximately **4-6 cases were completed per session**.

Phase 3: Facilitated Debriefing (15 minutes)
Faculty-led small-group debriefing sessions (8-10 learners) using a structured reflective framework encompassing **reaction, description, analysis, and application phases**. An advocacy-inquiry approach was employed to explore learner reasoning, correct misconceptions, and promote transfer of learning.

AI-Assisted Algorithm-Supported Adaptation Logic

The "AI-assisted" component refers to **predefined rule-based adaptive instructional functions** designed to personalize learning according to participant performance. The system automatically adjusted case difficulty, selected feedback pathways, and sequenced subsequent learning tasks based on learner responses using faculty-defined instructional rules.

Adaptive Thresholds:

Performance Accuracy	System Response
> 80%	Progress to advanced case with increased complexity, competing pathophysiological mechanisms, and multi-step reasoning challenges
60-80%	Maintain moderate complexity; standard progression
< 60%	Trigger scaffolding: simplified case variants, targeted conceptual prompts, expanded explanatory feedback

The adaptive system maintained learner success rates within an approximate **60-80% performance window** to balance cognitive challenge and learner confidence per cognitive load theory and self-efficacy principles.

Important clarification: The platform did NOT use autonomous content generation, machine learning prediction models, natural language processing, or independent clinical decision-making functions.

Physiological Systems Covered (8 Core Systems)

1. Cardiovascular System
2. Respiratory System
3. Renal System
4. Neurological System
5. Endocrine System
6. Gastrointestinal System
7. Musculoskeletal System
8. Integumentary System

Simulation Fidelity

- **Conceptual fidelity:** All scenarios developed and reviewed by physiology faculty for scientific accuracy and curricular alignment.

- **Psychological fidelity:** Realistic patient narratives, simulated vital signs, laboratory findings, and time-pressured decision points.
- **Environmental fidelity:** High-quality digital visualizations and dynamic graphical representations of physiological processes.

3.7 Control Group: Conventional Teaching

Participants assigned to the control group received **standard curriculum-based physiology instruction** over the same 12-week study period, covering equivalent physiological systems with comparable instructional exposure (~24 hours). Instruction comprised:

- Didactic lectures covering foundational physiological mechanisms, system integration, and applied physiological interpretation
- Prescribed textbook readings assigned weekly
- Faculty-guided tutorial sessions involving structured clarification of physiological concepts and small-group discussion
- Scheduled laboratory practicals involving supervised physiological measurements and observation

The control condition did **not** include adaptive case sequencing, algorithm-supported instructional adaptation, automated formative feedback, interactive simulation-based clinical reasoning tasks, animated physiological visualization environments, or structured simulation debriefing. Participants in the control group did not have access to the adaptive simulation platform during the study period.

Following study completion, optional access to selected simulation learning resources was offered to the control group to address ethical considerations related to educational equity.

3.8 Assessment & Outcome Measures

All outcomes were assessed at three predefined time points:

- **Baseline (Week 1, Time 1)** — prior to intervention
- **Post-Intervention (Week 13, Time 2)**
- **Follow-up (Week 17, Time 3)** — four weeks post-intervention

Assessments were administered **online** using a secure institution-approved platform under standardized testing conditions.

3.8.1 Primary Outcomes

1. Physiological Knowledge (Physiological Knowledge Test - PKT)

- 40-item multiple-choice assessment covering 8 core physiological systems
- Designed to evaluate higher-order conceptual application and physiological interpretation
- Cronbach's α = 0.89 (good internal consistency)
- Time Frame: Baseline, Post-Intervention, 4-week Follow-up

2. Physiological Reasoning Ability (Physiological Reasoning Ability Test - PRAT)

- Scenario-based assessment comprising clinical vignettes
- Tasks: hypothesis generation, interpretation of physiological data, application to management decisions
- Scored using a four-point analytic rubric (hypothesis generation, physiological explanation, diagnostic interpretation, management justification)
- Inter-rater reliability: ICC = 0.91 (excellent)
- Two blinded raters independently scored responses
- Time Frame: Baseline, Post-Intervention, 4-week Follow-up

3.8.2 Secondary Outcomes

3. Conceptual Understanding (Physiological Concepts Inventory - PCI)

- Faculty-developed physiology concept inventory distinguishing deep conceptual understanding from surface-level memorization
- Covers all 8 physiological systems
- Cronbach's α = 0.84 (good internal consistency)
- Higher scores indicate deeper conceptual understanding
- Time Frame: Baseline, Post-Intervention, 4-week Follow-up

4. Student Engagement (University Student Engagement Inventory - USEI)

- Assesses behavioral, emotional, and cognitive dimensions of learner engagement
- Higher scores indicate greater engagement
- Cronbach's α = 0.88
- Time Frame: Baseline, Post-Intervention, 4-week Follow-up

5. Cognitive Load (NASA Task Load Index - NASA-TLX)

- Multidimensional measure of perceived cognitive workload
- Higher scores reflect greater perceived workload and task demand
- Cronbach's α = 0.82
- Time Frame: Baseline, Post-Intervention, 4-week Follow-up

6. Academic Self-Efficacy (College Academic Self-Efficacy Scale - CASES)

- Adapted version assessing learner confidence in physiology-related academic tasks and simulation-based learning activities
- Higher scores indicate greater academic self-efficacy
- Cronbach's $\alpha = 0.86$
- Time Frame: Baseline, Post-Intervention, 4-week Follow-up

4. Statistical Analysis Plan (SAP)

All statistical analyses were performed using **IBM SPSS Statistics version 22.0** (IBM Corp., Armonk, NY, USA). All tests were two-tailed, with statistical significance set at **$\alpha = 0.05$**.

Effect size conventions:

- Cohen's d / f: 0.20 (small), 0.50 (medium), 0.80 (large)
- Partial eta squared ($\eta^2 p$): 0.01 (small), 0.06 (medium), 0.14 (large)

All randomized participants were included in final analyses according to the **intention-to-treat (ITT) principle**.

4.1 Primary Outcomes

Descriptive statistics:

- Normally distributed continuous data: mean and standard deviation (SD)
- Non-normally distributed data: median and interquartile range (IQR)
- Categorical data: frequencies and percentages

Assumption testing:

- Normality: Shapiro-Wilk test and visual inspection of Q-Q plots
- Homogeneity of variances: Levene's test
- Sphericity: Mauchly's test; Greenhouse-Geisser correction applied when violated ($p < 0.05$)
- Baseline equivalence: independent-samples t-tests (continuous) and chi-square tests (categorical)
- Missing data patterns: Little's MCAR test

Primary inferential analysis:

- **Repeated-measures ANOVA** to examine main effects of time, group, and time × group interaction for:
  - Physiological Knowledge Test (PKT)
  - Physiological Reasoning Ability Test (PRAT)
- Significance threshold: $p < 0.05$
- Post-hoc: **Bonferroni-adjusted pairwise comparisons** when significant effects identified
- Effect sizes: partial eta squared ($\eta^2 p$) for omnibus tests; Cohen's d for pairwise comparisons

Additional analysis:

- **Multiple linear regression** to explore predictors of follow-up physiological knowledge (PKT) scores, controlling for: baseline PKT, prior digital experience, prior AI tool exposure, post-intervention engagement (USEI), and post-intervention cognitive load (NASA-TLX)
- Multicollinearity assessed using tolerance values and variance inflation factors (VIF)

4.2 Secondary Outcomes

Repeated-measures ANOVA will be conducted for each secondary outcome:

- Physiological Concepts Inventory (PCI)
- University Student Engagement Inventory (USEI) — overall and subscales (Behavioral, Cognitive, Emotional)
- NASA Task Load Index (NASA-TLX)
- Academic Self-Efficacy (ASE/CASES)

Statistical significance threshold: $p < 0.05$. Bonferroni-adjusted post-hoc analyses will follow significant effects. Effect sizes reported using partial eta squared ($\eta^2 p$).

4.3 Missing Data

Six participants (three per group) were lost prior to the Time 3 follow-up assessment. Missing follow-up values for participants lost prior to the Time 3 assessment were handled using the **Last Observation Carried Forward (LOCF)** method in accordance with the intention-to-treat principle. Specifically, the most recent available participant outcome values were carried forward for follow-up analyses to preserve randomized group allocation and maintain complete repeated-measures datasets for statistical analysis.

Participants who withdrew from intervention participation permitted retention and analysis of previously collected de-identified study data in accordance with the approved consent process and institutional ethics approval.

5. Informed Consent Form (ICF)

Study Title: Effect of AI-Assisted Rule-Based Adaptive Simulation on Physiology Learning Outcomes Among Health Science Students: A Randomized Controlled Trial

Principal Investigator: Mr. Jeevarathinam Thirumalai, Saveetha Institute of Basic Medical Sciences, SIMATS, Chennai, India

Ethics Approval: Institutional Scientific Review Board, SIMATS — Approval No. 24/032/2025/SR/SIBMS

You are being invited to participate in a research study. Before you decide whether to take part, it is important that you understand what the study involves. Please read this information carefully and discuss it with others if you wish.

What is the study about?
This study aims to evaluate the effectiveness of an AI-assisted adaptive simulation learning environment for teaching physiology compared with conventional instruction among undergraduate health science students.

What will participation involve?
If you agree to take part, you will be randomly assigned to one of two groups:

- **AI-Assisted Simulation Group:** Receive physiology instruction through an interactive screen-based adaptive simulation platform for 2 hours per week over 12 weeks (24 hours total).
- **Conventional Instruction Group:** Receive standard curriculum-based physiology instruction (lectures, tutorials, lab practicals) for 24 hours over 12 weeks.

You will be assessed at three time points: before the intervention (baseline), immediately after (post-intervention), and at a four-week follow-up. Assessments include a knowledge test, a clinical reasoning task, and questionnaires measuring engagement, cognitive load, and self-confidence.

Time commitment: Approximately 12 weeks of participation with three assessment sessions.

What are the possible risks?
The researchers do not anticipate any significant risk from participation in this research study.

If assigned to the AI simulation group, you may experience increased cognitive demand. If assigned to the conventional group, optional access to simulation resources will be offered after the study concludes.

What are the benefits?
Participation may enhance your physiological knowledge, clinical reasoning skills, and academic confidence. Findings may contribute to evidence-based improvements in health sciences education.

5.1 Rights and Risks to Participants

Rights:

- Participation in this study is entirely **voluntary**.
- You may decide to stop participating at any time without explanation and without affecting your academic standing.
- You have the right to omit or refuse to answer any question.
- You have the right to ask questions about the study procedures at any time by contacting the principal investigator.
- Participation does not carry any remuneration or reimbursement.

Risks:

- The researchers do not anticipate any significant physical, psychological, or academic risk from participation in this study.
- Increased cognitive demand may be experienced in the simulation group, which is consistent with normal educational challenge.

For questions or concerns, please contact:
Principal Investigator: Mr. Jeevarathinam Thirumalai
Institution: Saveetha Institute of Basic Medical Sciences, SIMATS, Chennai, India
Ethics Board: SIMATS Institutional Scientific Review Board — Approval No. 24/032/2025/SR/SIBMS

Participant Declaration:
I confirm that I have read and understood the information above. I have had the opportunity to ask questions and all my questions have been answered satisfactorily. I understand that my participation is voluntary and that I may withdraw at any time without consequence.

☐ I consent to participate in this study.
☐ I consent to my previously collected de-identified data being retained for analysis if I withdraw.

Name (Participant): ______________________________
Date: ______________________________
Signature: ______________________________

Investigator Declaration:
I confirm that I have explained the study to the above participant and answered their questions to the best of my ability.

Name (Investigator): ______________________________
Date: ______________________________
Signature: ______________________________

5.2 Privacy and Confidentiality

All participants will be **de-identified** and assigned a unique ID number at the time of enrollment. No personally identifiable information will be included in any published or publicly accessible document. All data will be stored securely using institutional data management protocols. Access to identifiable data will be restricted to the principal investigator and authorized research personnel only. Results will be reported at a group level and will not allow identification of individual participants. Data will be retained in accordance with institutional and ethical guidelines for the duration required following study completion.

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