Case-Based vs. Lecture-Based Learning for Ischemic Stroke Education: A Randomized Controlled Trial in Argentine Medical Students

Trial registration

ISRCTN31260053 (prospectively registered)

Protocol version and date

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None. The study was entirely investigator-initiated and self-funded.

Conflicts of interest

None declared.

Background and rationale

Cerebrovascular diseases rank among the leading causes of death and disability worldwide, with rising incidence in low- and middle-income countries. Effective medical education on acute ischemic stroke (AIS) is critical, particularly given the high prevalence of “neurophobia” among medical students and physicians. Systematic reviews suggest that case-based learning (CBL) enhances student satisfaction and may improve knowledge acquisition and clinical reasoning compared with traditional lecture-based learning (LBL). This randomized controlled trial evaluates whether CBL is superior to LBL for teaching AIS to fourth-year medical students.

Objectives

Primary objective

1. To test whether case-based learning (CBL) improves the acquisition of knowledge about acute ischemic stroke compared with lecture-based learning (LBL) in fourth-year medical students, measured by multiple-choice questionnaire (MCQ) scores immediately post-intervention.

Secondary objectives

1. To determine whether differences in knowledge acquisition between CBL and LBL persist at 6 months (knowledge retention).
2. To evaluate whether there are differences in clinical skills for AIS management between CBL and LBL, as measured by Objective Structured Clinical Examination (OSCE) scores.
3. To analyze whether there are differences in student satisfaction with the AIS learning experience between CBL and LBL, as measured by a 5-point Likert scale survey.

Study design

Single-centre, randomized, single-blind (outcome assessors), parallel-group, controlled trial. Allocation ratio 1:1.

Setting

Facultad de Medicina, Universidad Nacional del Nordeste (UNNE) and Hospital Escuela José Francisco de San Martín, Corrientes, Argentina.

Participants

- Inclusion criteria: Fourth-year medical students enrolled in the Neurology course (Medicina II) at UNNE, aged 19–27 years, willing to participate and providing written informed consent.
- Exclusion criteria: Students retaking the course.

Sample size

90 students (45 per group). Calculation based on previous studies expecting a 5–7.5-point difference in MCQ scores (SD 7.5), 80% power, α=0.05, and 20% attrition.

Randomization and blinding

Computer-generated random number sequence with allocation concealment using sealed opaque envelopes managed by an independent coordinator. Outcome assessors (professors and teaching assistants) were blinded to group allocation and had no involvement in the interventions.

Interventions

Both arms received identical bibliographic material on AIS. Total teaching time was 90 minutes.

- Experimental arm (CBL): Two interactive 45-minute case-based learning sessions (total 90 min) using real clinical scenarios of ischemic stroke (presentation, diagnosis, acute management, secondary prevention). Facilitated by the principal investigator with active student participation.
- Control arm (LBL): One 90-minute traditional lecture on the same content delivered by the principal investigator.

Outcomes:

Primary Outcome

- Knowledge acquisition – score on a 50-item single-best-answer MCQ (0–50 points) administered immediately post-intervention. The same MCQ was used pre-intervention, post-intervention and at 6 months.

Secondary outcomes:

- Knowledge retention – MCQ score (total 0–50) at 6 months.
- Clinical skills – OSCE score (5 stations, 10 points each, total 0–50) performed 1 week post-intervention. Examiners were blinded.
- Satisfaction – 5-point Likert scale survey (1 = strongly disagree to 5 = strongly agree) administered 1 week post-intervention.

SPIRIT 2025 schedule of enrolment, interventions, and assessments

Timepoint	Enrolment	Allocation	Intervention (Week 2)	Post-intervention (Week 3)	Follow-up (Month 6)
Eligibility & consent	X				
Randomization		X			
Pre-intervention MCQ	X				
Intervention (CBL or LBL)			X		
Post-intervention MCQ				X	
OSCE				X	
Satisfaction survey				X	
MCQ at 6 months					X

Data collection and management

All data were collected anonymously using coded IDs. The principal investigator maintained the key in a password-protected file. Data will be stored on a secure computer for 1 year after study completion and then deleted.

Statistical analysis plan

The primary analysis will test the hypothesis H_0: $\mu D = 0$ vs H_a: $\mu D > 0$ (difference in mean MCQ post-intervention scores between CBL and LBL groups) using an independent samples t-test (or non-parametric equivalent if normality assumptions not met), under the central limit theorem. Secondary analyses will include repeated-measures approaches for retention and appropriate tests for OSCE and Likert scores. A detailed Statistical Analysis Plan will be finalized and documented prior to database lock.

Ethics approval

Approved by the Comité de Bioética en Investigación de Ciencias de la Salud – Facultad de Medicina – UNNE (Reference 33/25, date 28/08/2025). Written informed consent was obtained from all participants. Participation was voluntary; assessments were formative and did not affect academic grades. The study complies with the Declaration of Helsinki.

Dissemination

Results will be submitted for publication in a peer-reviewed medical education journal and presented at national/international conferences. The protocol is registered in ISRCTN to promote transparency.

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