# Study Protocol and Statistical Analysis Plan

# Effect of AI Critical Appraisal Training on Critical Thinking in Nursing Students

**April 2nd, 2026**

## 1. Study Synopsis

- **Design:** Multi-cycle, longitudinal, cluster randomized controlled trial.
- **Population:** Undergraduate nursing students enrolled in consecutive semesters.
- **Groups:** For each study cycle, intact class clusters will be randomly allocated to one of two groups:
    - **Experimental Group:** Receives “AI Critical Appraisal Training”, where students use AI tools to analyze cases and provide structured critiques of the AI-generated output.
    - **Control Group:** Receives “Traditional Case Analysis Training”, completing the same cases without the use of AI tools.
- **Intervention:** An 8-week program integrated into a surgical nursing course. One structured case assignment is completed every two weeks (4 assignments total).
- **Primary Objective:** To evaluate the effect of AI critical appraisal training compared to traditional teaching on improving nursing students' disposition toward critical thinking.
- **Primary Outcome:** Change in total score from baseline to week 8 on the Chinese Version of the Critical Thinking Disposition Inventory (CTDI-CV).
- **Secondary Outcomes:** Changes in AI literacy and clinical reasoning ability, end-of-semester theoretical exam scores, and qualitative analysis of students' critical appraisal texts.

## 2. Study Design

This is a prospective, parallel-group, assessor-blinded, cluster randomized controlled trial. The study will be rolled out over multiple academic semesters, with each semester constituting an independent research cycle to accumulate evidence.

## 3. Study Population

- **Inclusion Criteria (Applicable per cycle):**

  ① Full-time undergraduate nursing students.

  ② Enrolled in the target surgical nursing course for that cycle.

  ③ Aged 18 years or older.

  ④ Provide voluntary written informed consent.

- **Exclusion Criteria (Applicable per cycle):**

  ① No-degree students or auditors.

  ② Unable to participate in the full study process.

  ③ Students who do not take the final theoretical examination.

  ④ Students who do not complete the pre- and post-intervention questionnaires.

**4. Interventions**

- **Experimental Group (AI Critical Appraisal Training):**
  - **Format:** Completion of 4 structured case assignments over 8 weeks.
  - **Core Task:** For each case, students use an AI tool and submit a report containing: (1) the complete dialogue log with the AI, (2) critical annotations on the AI's responses (identifying at least 3 debatable points or errors with corrections and justifications), and (3) a personal reflection.
- **Control Group (Traditional Case Analysis Training):**
  - **Format:** Completion of the same 4 case assignments over the same 8-week period.
  - **Core Task:** Without using AI tools, students analyze cases by consulting traditional resources (e.g., textbooks, academic databases) and submit a

report containing: (1) their self-generated answers, (2) a personal reflection, and (3) a declaration confirming no AI use.

**5. Outcome Measures**

- **Primary Outcome Measure:**
    - **Instrument:** Chinese Version of the Critical Thinking Disposition Inventory (CTDI-CV).
    - **Timepoints:** Baseline (Week 1, pre-intervention) and Post-intervention (Week 8).
- **Secondary Outcome Measures:**

① **AI Literacy:** Score on the Artificial Intelligence Literacy Scale for Chinese College Students (AILS-CCS), measured at baseline and week 8.

② **Clinical Reasoning Ability:** Score on the Chinese Version of the Clinical Reasoning and Reflection Self-Assessment Scale, measured at baseline and week 8.

③ **Theoretical Knowledge:** Score on a unified, end-of-semester written examination.

④ **Process Evaluation:** Qualitative content analysis of the critical annotation texts submitted by students in the experimental group.

**6. Statistical Analysis Plan**

- **Principles:** Intent-to-treat analysis will be applied. The clustered nature of the design will be accounted for in all analyses.
- **Primary Analysis:** A linear mixed-effects model will be used to compare the change in the primary outcome between groups, with class cluster included as a random effect.
- **Secondary Analyses:** Similar models will be used for secondary quantitative

outcomes. Thematic analysis will be conducted for qualitative data.

## 7. Ethics and Data Management

- This study has been submitted for review and approval to the Biomedical Ethics Committee of Chengdu Medical College.
- Participation is entirely voluntary. The informed consent process is separated from course grading.
- All collected data will be de-identified and stored confidentially.

## 8. Study Timeline

- **Overall Duration:** March 2026 to August 2028.
- **Phase I (Preparation & Registration):** January - February 2026.
- **Phase II (Pilot Survey):** March 2026.
- **Phase III (Longitudinal Implementation):** April 2026 to December 2027 (multi-cycle intervention and data collection).
- **Final Analysis Completion:** August 2028 (anticipated).