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Study Protocol and Statistical Analysis Plan

Official Title: The Effect of Digital Interactive and Face-to-Face Peer Support on Medical Students' Clinical Skill Performance, Reflection Skills, and Retention of Clinical Skills

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1. Synopsis

- Design: Interventional, randomized, parallel-group, three-arm educational trial.
- Arms: (A) Digital interactive peer support; (B) Face-to-face peer support; (C) Standard training (control).
- Primary Endpoint: Objective Structured Clinical Examination (OSCE) total score immediately post-intervention (points; higher is better).
- Secondary Endpoints: Reflection skills scale total score immediately post-intervention; Retention assessed by a follow-up OSCE at a predefined interval (e.g., 8–12 weeks).
- Setting: Clinical Skills Laboratory within a Faculty of Medicine in Türkiye.
- Population: Adult medical students meeting eligibility criteria.
- Allocation: Approximately 1:1:1; no masking.
- Estimated/Actual Enrollment: About 100 participants (retrospective registration of a completed trial).

2. Background and Rationale

Peer support is widely used in health professions education to promote practice, feedback, and reflection. Digital interactive platforms may expand access and flexibility compared with traditional face-to-face sessions. This study evaluates whether structured digital peer support is non-inferior or superior to face-to-face peer support, and whether either approach improves clinical skill performance compared with standard training.

3. Objectives

Primary Objective. Compare post-intervention clinical skill performance between arms using OSCE total scores.

Secondary Objectives. Compare reflection skills between arms immediately post-intervention; evaluate retention of clinical skills at follow-up OSCE; explore relationships between outcomes and exposure to peer support.

4. Endpoints

Primary Endpoint. OSCE total score immediately post-intervention (points; higher scores indicate better performance).

Secondary Endpoints. (i) Reflection skills total score immediately post-intervention (points; higher is better); (ii) Follow-up OSCE total score at a predefined interval to assess retention.

5. Trial Design

Individually randomized, parallel assignment with three arms. Participants are assigned in approximately equal numbers to the digital, face-to-face, or standard training arms. Interventions occur within routine clinical skills teaching sessions. No masking is used.

6. Study Setting

University-based Clinical Skills Laboratory and associated teaching rooms in Türkiye.

7. Eligibility Criteria

Inclusion Criteria

- Enrolled medical students [specify year(s)].
- Age ≥18 and able to provide informed consent.
- Sufficient proficiency in the language of instruction.
- Access to the digital platform (for allocation to the digital arm).
- Availability for post-intervention and follow-up assessments.

Exclusion Criteria

- Prior formal certification or extensive training in the targeted clinical skills.
- Inability to attend scheduled peer-support sessions (digital or face-to-face).
- Conditions preventing participation in OSCE/assessment procedures.

8. Interventions

Digital Interactive Peer Support (Behavioral). Structured peer learning via an online platform (modules, quizzes, discussion forums, and peer feedback).

Face-to-Face Peer Support (Behavioral). Structured in-person peer sessions with guided practice, observation, and formative feedback.

Standard Training (Control; Behavioral). Usual curriculum-based clinical skills training without additional structured peer support.

9. Procedures and Schedule

Following consent and baseline administrative checks, students receive instruction according to allocation. Outcome assessments include an immediate post-intervention OSCE and a validated reflection skills questionnaire. A follow-up OSCE is administered at a predefined interval (e.g., 8–12 weeks) to assess retention. Assessors use standardized checklists and instructions. No

investigational products are used.

10. Data Management and Confidentiality

Data are recorded using de-identified codes and stored on secure institutional systems. Only authorized personnel have access to identifiable information. Aggregated results may be disseminated in publications without personal identifiers.

11. Ethics and Oversight

The study was reviewed by an institutional ethics committee. Participation is voluntary, and students may withdraw at any time without academic penalty. The study involves minimal risk educational procedures. A Data Monitoring Committee is not planned for this low-risk trial.

Statistical Analysis Plan (SAP)

This SAP prespecifies analysis populations, endpoints, statistical tests, missing data handling, and multiplicity control. Analyses will be conducted using a two-sided significance level of 0.05.

12. Analysis Populations

Intent-to-Treat (ITT): All randomized students with at least one post-intervention assessment.

Per-Protocol (PP): Subset without major protocol deviations.

13. Descriptive Statistics

Continuous variables will be summarized with mean, standard deviation, median, minimum, and maximum; categorical variables with counts and percentages.

14. Primary Endpoint Analysis

Between-arm comparison of immediate post-intervention OSCE total scores: if assumptions are met, one-way ANOVA; otherwise, Kruskal–Wallis test. If the omnibus test is significant, perform pairwise comparisons with multiplicity adjustment (e.g., Bonferroni or Holm).

15. Secondary Endpoint Analyses

Reflection skills total score will be analyzed analogously to the primary endpoint. Retention of skills will be evaluated by comparing follow-up OSCE total scores between arms at the predefined time point using ANOVA or Kruskal–Wallis as appropriate.

16. Covariate-Adjusted Analyses (Exploratory)

If available, models may adjust for prespecified covariates such as prior academic performance, baseline checklist items, or attendance. Model diagnostics will be examined; if assumptions are violated, robust or nonparametric alternatives will be considered.

17. Missing Data

Patterns of missingness will be described. Primary analyses will use available cases. Sensitivity analyses may include multiple imputation or nonparametric methods consistent with the primary analysis framework.

18. Multiplicity

For multiple pairwise comparisons following a significant omnibus test, p-values will be adjusted (e.g., Bonferroni/Holm) to control the family-wise error rate.

19. Statistical Software

Analyses will be performed using standard statistical software (e.g., SPSS, R, or Python).

20. Administrative Information

Sponsor/Institution: [University / Faculty of Medicine]. Study officials and contacts are listed in the trial registry record. This public document does not include participant names or personally identifiable information.

Any deviations from this plan will be documented in the results submission. This version supersedes prior versions as of the Document Date.