Official Title: Effectiveness of artificial intelligence-assisted training with real-time visual feedback on hand hygiene competency among newly hired healthcare workers

NCT Number: Not yet assigned

Protocol ID: 2025-2256-01

Document Date: 2026-08-01

Document Type: Study Protocol with Statistical Analysis Plan

1. Background and Rationale

Healthcare-associated infections (HAIs) remain a major threat to patient safety and impose substantial morbidity, mortality, and healthcare costs. Hand hygiene is the single most effective and cost-efficient measure for preventing HAIs. However, conventional hand hygiene training predominantly relies on didactic instruction and subjective observation. These methods provide delayed feedback and are limited by inter-observer variability and the Hawthorne effect. As a result, many healthcare workers do not achieve or maintain adequate hand hygiene competency.

Recent advances in artificial intelligence (AI) and computer vision offer new opportunities for precision skills training. AI-assisted training systems can perform real-time motor analysis, deliver individualized feedback, and generate objective, reproducible quantitative assessments. Within hand hygiene, AI-based platforms can recognize and evaluate the discrete steps of the WHO-recommended handwashing protocol, enabling automated, real-time corrective guidance. However, rigorous randomized controlled trials comparing AI-assisted training with conventional instructor-led training for hand hygiene technique acquisition remain scarce.

This study was designed to evaluate whether AI-assisted training with real-time visual feedback improves hand hygiene competency among newly hired healthcare workers compared with conventional instructor-led training.

2. Objectives and Hypothesis

Primary Objective

To compare the effectiveness of AI-assisted training with real-time visual feedback versus conventional instructor-led training in improving overall hand hygiene competency among newly hired healthcare workers.

Secondary Objective

To compare scores for each of the 12 sub-steps of the WHO seven-step hand hygiene technique between the two groups.

Hypothesis

We hypothesized that AI-assisted training with real-time visual feedback would yield significantly higher overall hand hygiene competency scores than conventional instructor-led training.

3. Study Design

This was a single-center, randomized controlled trial conducted at Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, Hangzhou, China, during the new employee orientation period in August 2025. A total of 260 newly hired healthcare workers were enrolled and randomly allocated in a 1:1 ratio to either the control group (n = 130) or the AI-assisted group (n = 130).

The study design and participant flow are summarized in Fig. 1 of the main manuscript. Both groups initially completed a standardized 30-minute baseline didactic session covering hand hygiene standard operating procedures (SOPs) and assessment criteria, without hands-on practice. Immediately thereafter, the control group underwent conventional instructor-led practical training (45 minutes), while the intervention group received AI-assisted training with real-time visual feedback displayed on an integrated screen (45 minutes). All participants subsequently completed a competency assessment using the identical AI platform under standardized conditions.

4. Participants

Inclusion Criteria

- Full-time employment at Sir Run Run Shaw Hospital, Zhejiang University School of Medicine
- Starting employment within the August 2025 new employee orientation cohort
- Voluntary participation with written informed consent

Exclusion Criteria

- Prior attainment of any formal hand hygiene operation certification
- Previous participation in structured competency-based hand hygiene training with objective skill assessment
- Prior employment as a licensed healthcare worker in any clinical setting

Although some participants had received theoretical instruction on hand hygiene during their pre-service education, none had undergone systematic, competency-based hand hygiene training incorporating real-time performance feedback.

5. Randomization and Allocation

Participants were randomly allocated in a 1:1 ratio to the control group or the AI-assisted group. Allocation was performed during the orientation period. No blinding was applied to participants or instructors. However, the primary outcome was assessed automatically by the AI platform, which ensured objective and blinded evaluation of the primary endpoint.

6. Interventions

Both groups first completed a standardized 30-minute didactic session covering hand hygiene SOPs and assessment criteria. No hands-on practice was included in this session.

Control Group

Participants received 45 minutes of conventional instructor-led practical training under the usual apprenticeship-style teaching model. No AI-based real-time visual feedback was provided.

AI-Assisted Group

Participants received 45 minutes of AI-assisted practical training. An overhead high-definition camera and a local edge-computing unit captured handwashing movements at 12 frames per second. A real-time display screen provided visual feedback, allowing participants to monitor their performance and correct movements immediately. The AI platform evaluated the WHO seven-step handwashing technique, decomposed into 12 sub-steps.

7. AI-Based Hand Hygiene Assessment System

The AI-based assessment system comprised an overhead high-definition camera, a local edge-computing processing unit running the AI inference engine, and a real-time display screen for visual feedback. The system captured video at 12 frames per second and employed a YOLOv8-based deep learning object detector to recognize and classify handwashing movements.

The platform was designed to evaluate the WHO-recommended seven-step handwashing technique. To enable granular performance quantification, the seven steps were further decomposed into 12 discrete sub-steps:

- Unilateral movements assessed independently for the left and right hands: dorsum rubbing, locked fingers, thumb rotation, fingertip rubbing, and wrist rotation

- Bilateral movements evaluated as single sub-steps: palm-to-palm rubbing and interlaced fingers

For each sub-step, the algorithm tracked two variables per handwashing station:

1. The cumulative number of frames in which that sub-step was detected
2. A ranked list retaining the highest confidence scores observed for that sub-step, capped at 24 entries (corresponding to 12 frames/second × 2 seconds)

A sub-step was deemed confirmed only when the cumulative detected frames exceeded 24 frames (i.e., >2 seconds of cumulative detection). The score for each confirmed sub-step was calculated as the mean of the retained confidence scores multiplied by 100, yielding a range of 0 to 100. If the scores list contained fewer than 24 entries, the sub-step received a score of 0. The overall hand hygiene competency score was computed as the arithmetic mean of all 12 sub-step scores, rounded to one decimal place.

8. Outcome Measures

Primary Outcome Measure

Overall hand hygiene competency score assessed immediately after training using the AI-based platform. The platform evaluated the WHO seven-step technique, decomposed into 12 sub-steps. Each sub-step was scored from 0 to 100 based on detection confidence. The overall score was the arithmetic mean of all 12 sub-step scores, rounded to one decimal place. Higher scores indicate better hand hygiene competency.

Secondary Outcome Measures

Scores for each of the 12 sub-steps of the WHO seven-step hand hygiene technique. The 12 sub-steps were:

- Palm-to-palm rubbing
- Palm-to-opisthenar rubbing, left
- Palm-to-opisthenar rubbing, right
- Interlaced fingers
- Locked fingers, left
- Locked fingers, right
- Thumb rubbing, left
- Thumb rubbing, right
- Fingertip rubbing, left
- Fingertip rubbing, right

- Wrist rubbing, left
- Wrist rubbing, right

Each sub-step was scored from 0 to 100.

Other Pre-Specified Outcome Measure

Subgroup analyses of overall hand hygiene competency score by sex (female, male) and occupation (physician, nurse, other).

9. Sample Size

A total of 260 newly hired healthcare workers were enrolled, with 130 participants in each group. No formal power calculation was performed for this study. The sample size was based on the number of newly hired healthcare workers available during the August 2025 orientation period.

10. Statistical Analysis Plan

Analysis Populations

All randomized participants who completed the post-training competency assessment were included in the analysis.

Descriptive Statistics

Continuous variables are reported as medians with interquartile ranges (IQR). Categorical variables are reported as frequencies with percentages.

Primary Analysis

The primary outcome was the overall hand hygiene competency score. Between-group comparisons were performed using the Mann-Whitney U test.

Secondary Analyses

Scores for each of the 12 sub-steps were compared between groups using the Mann-Whitney U test.

Subgroup Analyses

Subgroup analyses were performed for sex (female, male) and occupation (physician, nurse, other). Between-group comparisons within each subgroup were performed using the Mann-Whitney U test.

Categorical Variables

Categorical variables were analyzed using the chi-square test or Fisher's exact test, as appropriate.

Missing Data

No imputation was performed. Participants with missing outcome data were excluded from the corresponding analysis.

Statistical Significance

All statistical tests were two-sided, with statistical significance defined as a P-value < 0.05. No adjustment for multiple comparisons was applied to secondary or subgroup analyses; these analyses were considered exploratory.

Software

Analyses were conducted using R software version 4.5.1.

11. Ethical Considerations

The study protocol was reviewed and approved by the Clinical Research Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine (approval no. 2025-0226). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was obtained from each participant.

12. Data Availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

13. Limitations

This was a single-center study conducted at a tertiary academic medical center in China. The assessment captured only immediate post-training competency, so long-

term skill retention was not evaluated. The AI-generated competency scores are a proxy measure of procedural fidelity rather than a direct indicator of microbial load reduction or clinical efficacy. Participants and instructors were not blinded.