1. Trial Name: Analysis of the Effect of Pre-course Videos on Improving Clinical Skills in Emergency Ultrasound Training

NCT number: VGHTPE IRB ID: 2024 - 06 - 006B

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2. Trial Location:

Trial Location: Department of Emergency Medicine, Taipei Veterans General Hospital

3. Research Background:

The current status of the studied disease, including its natural course, available treatments, and prognosis. Point-of-Care Ultrasound (POCUS) has become increasingly popular in recent years. In clinical care, beyond traditional physical examination tools like stethoscopes, reflex hammers, or penlights, ultrasound has gained a significant role. Proper ultrasound training rapidly aids in clinical decision-making and diagnosis. However, the quality of ultrasound training is often limited by the number of ultrasound machines, the scarcity of clinical instructors, and the high number of trainees, which dilutes the opportunities and time for hands-on practice, thereby affecting teaching quality. Efficiently imparting ultrasound operational skills through hands-on practice has become a major challenge for improving training quality. A teaching randomized controlled trial published in BMC Medical Education in 2020 discussed the importance of video or peer empowerment in ultrasound education in medical schools. Usually supervised by experienced faculty, bedside exams or peer practice sessions are conducted. However, due to the high number of enrolled trainees, one-on-one mentoring opportunities are often unavailable. To overcome this obstacle, using instructional videos supplemented by peer teaching conducted by trained trainees has proven feasible and effective. However, this study focused on training ultrasound techniques for diagnosing abdominal and cardiac diseases and did not explore the impact of videos on training for invasive ultrasound-guided procedures. There are also related discussions on how to shoot instructional videos for procedural skills, with some articles suggesting that first-person point-of-view (POV) filming could enhance realism and learning effectiveness. For instance, in the UK, medical schools have used GoPro cameras to record first-person POV during ward rounds, handovers, and patient condition explanations, providing an immersive and reproducible educational experience for large groups of learners with less time and resource investment compared to traditional small-group simulations. Additionally, a study in nursing education, published in the fields of cognitive learning and experimental psychology, compared pre- and post-test results of technical training under three video conditions: face-

to-face view, shoulder-overview, and mixed view (alternating face-to-face and shoulder-overview for each step). A control group without video viewing was also included. The results showed that learners in the mixed view group performed better than those in other groups. Learners in the face-to-face and shoulder-overview groups also performed better than the control group, but there was no significant difference between these two groups. Moreover, learners in the mixed view group reported higher confidence in safely and accurately completing the procedures.

4. Research Objectives:

Primary Objective: Evaluate the effectiveness of pre-class video learning in enhancing ultrasound teaching efficiency (i.e., differences between groups that watched the pre-class video and the control group that did not). Secondary Objective: Investigate the impact of pre-class instructional videos using first-person POV filming versus face-to-face filming on learning outcomes in ultrasound skills training.

5. Research Steps:

Recruit PGY physicians and medical interns at our hospital who are highly interested in learning emergency ultrasound-guided central venous catheter insertion. Randomly assign participants into three groups based on a random number table: a group watching first-person POV operational videos, a group watching face-to-face operational videos, and a group not watching any videos before the class. The video-watching groups will receive an email with the video one week before the class, while the control group will receive a general pre-class reminder notification. On the day of the class, participants will fill out a questionnaire regarding basic information, self-assessment of learning skills, and whether they watched the pre-class video. After completing the questionnaire, participants will immediately undergo a pre-test, performing operations on models with ultrasound while being recorded. Instructors will assess the participants' performance using a skills checklist. This will be followed by one-on-one teaching, where instructors will provide detailed guidance on each operational step, and then a post-test where participants independently complete the ultrasound-guided central venous catheter insertion and record the results using the skills checklist. After the teaching session, a post-test questionnaire will be administered to assess satisfaction and self-confidence in performing the procedure.

6. Research Design:

1. Design Type: Parallel study design.

2. **Control Group:** Yes, the group not watching pre-class videos. The control group will receive the same quality and content of face-to-face teaching during the actual operational skills course.
3. **Blinding Method:** Single-blind. The instructor evaluating the pre- and post-test performance will not know the group assignment of the participants.
4. **Random Assignment:** To ensure that late-joining participants do not have a better foundational ultrasound skill level and to maintain group size balance, we will use blocked randomization with a block size of 3:
    - Block size=3 and Treatment=3, resulting in 6 possible assignments: 0=ABC, 1=CAB, 2=BAC, 3=ACB, 4=BCA, 5=CBA
    - A: No pre-class video group
    - B: Face-to-face operational video group
    - C: POV first-person operational video group Random number tables generated by computer (0-5) will assign participants to the above treatment orders, and assistants will distribute the appropriate pre-class videos and reminders.

7. Subjects:

1. **Selection Criteria:** PGY physicians and medical interns at our hospital who voluntarily enroll.
2. **Exclusion Criteria:** None.
3. **Number of Subjects:** Based on similar studies in nursing education comparing different video modalities for learning catheter placement (Table 1), we estimate the number of subjects using one-way ANOVA power analysis, setting α=0.05 and power at 0.8, with within-group variance set at 256:
    - Table 1. Estimated effect size and sample size based on literature:
        - Control group average: 62.0
        - Face-to-face video group average: 89.8
        - POV video group average: 99.4
        - High effect size: Each group requires 5 participants
        - Low effect size: Each group requires 24 participants Therefore, this study conservatively estimates needing 24 participants per group, totaling 72 participants for ANOVA analysis.

8. Research Methods:

1. **Teaching Method:** On the day of the class, participants will fill out a questionnaire (Attachment 1) regarding basic information, self-assessment of learning skills, and

whether they watched the pre-class video. After completing the questionnaire, participants will immediately undergo a pre-test, performing operations on models with ultrasound while being recorded. Instructors will assess the participants' performance using a skills checklist (Attachment 2). This will be followed by one-on-one teaching, where instructors will provide detailed guidance on each operational step, and then a post-test where participants independently complete the ultrasound-guided central venous catheter insertion and record the results using the skills checklist. After the teaching session, a post-test questionnaire (Attachment 3) will be administered to assess satisfaction and self-confidence in performing the procedure.

2. Concurrent Therapy: None.
3. Clinical Observations: The scores from the pre- and post-tests and the questionnaire responses will serve as the observational indicators.
4. Follow-up Schedule: Follow-up is completed after recording the results of the teaching activity.
5. Primary Efficacy or Evaluation Indicators:
    - Skills checklist score (Attachment 1).
    - Significant improvement in the skills checklist score for the intervention group compared to the control group.

9. Adverse Event Management:

1. Criteria and Incidence of Adverse Events: This teaching program employs standardized one-on-one teaching, ensuring no loss of learning opportunities for participants. The ultrasound and needle tools are used on models, posing no physical harm to participants. Therefore, there are no adverse physical effects.
2. Reporting Method: If participants are dissatisfied or need to report issues, the contact information of the instructors will be provided in the notification email and questionnaire for participants to communicate their concerns.
3. Handling Method: The teaching activity is beneficial for participants' skill enhancement and poses no harm. If there is any dissatisfaction with the teaching design, the instructors will communicate with participants and make necessary adjustments.

10. Subject Rights:

1. Safety Maintenance and Insurance: Participants will not suffer any harm.
2. Special Matters and Others: None.

11. Statistical Analysis:

1. **Descriptive Statistics:** Emphasize clinical significance, such as describing the expected treatment effects or the magnitude of treatment differences.
    - Chi-square test, Yates' correction, or Fisher's exact test will be used to compare categorical variables. Student’ s t-test or Mann-Whitney rank-sum test will be used to analyze continuous variables. R software will be used for statistical analysis. A P-value < 0.05 will be considered statistically significant.
2. **Inferential Statistics:** Statistical methods for testing the primary efficacy indicators.
    - One-way ANOVA or Kruskal-Wallis test will be used to compare means of continuous data among the three groups. A P-value < 0.05 will be considered statistically significant. Multiple comparison corrections will be considered for pairwise comparisons between groups if needed.
3. **Interim Analysis:** No interim analysis will be conducted.