Taipei Veterans General Hospital Clinical Trial/Research Plan

Participant Consent Form

You are invited to participate in this clinical trial/research study. This form provides you with relevant information about the study. The principal investigator or an authorized representative will explain the details of the trial/research and answer any questions you may have. Please do not sign this consent form until all your questions have been satisfactorily answered.You do not need to decide immediately whether to participate in this study. Please take the time to carefully consider your decision before signing. You must sign the consent form before participating in the study.If you agree to take part, this document will serve as a record of your consent. Even after giving your consent, you may withdraw from the study at any time without providing a reason.

Project Number:
Project Title: Analysis of the Effect of Pre-course Videos on Improving Clinical Skills in Emergency Ultrasound Training

Study Institution:
Taipei Veterans General Hospital (Department of Emergency Medicine)
Principal Investigator:
Dr. Po-Hsiang Liao, Department of Emergency Medicine (0958-516-762)
24-Hour Emergency Contact and Phone Number for This Study:
Dr. Po-Hsiang Liao (0958-516-762)

Subject's Name:
Gender: Date of Birth:
National ID Number:
Medical Record Number:
Mailing Address:
Contact Phone Number:
Emergency Contact Person: Phone:
Mailing Address:

Concise and focused presentation of the key information

Ultrasound training is currently limited by the availability of ultrasound machines, a shortage of clinical instructors, and a high number of trainees, resulting in diluted opportunities and time for hands-on practice, which affects the overall quality of education. Effectively teaching ultrasound operation skills through hands-on methods has become a key issue in improving training quality. This study will recruit physicians from our hospital who have a strong interest in learning ultrasound-guided central venous catheter (CVC) insertion in the emergency setting. It aims to evaluate the effectiveness of pre-course instructional videos in enhancing ultrasound education, and to explore the impact of using first-person point-of-view (POV) versus face-to-face filming techniques on learning outcomes.The trial will adopt a blocked randomization design with a block size of 3, assigning participants randomly into three groups with equal probability (1/3 each):POV video group (watching a first-person perspective instructional video),Face-to-face video group (watching a side-view instructional video),Control group (no video viewing prior to the training session).On the day of the training, participants will undergo a pre-test before the hands-on session, receive one-on-one instruction, and then complete a post-test.This training activity is expected to enhance participants' skills without affecting their learning rights. Participation will not influence routine evaluations, and the scores from this study will not be used for academic performance assessments by the education department. Furthermore, all ultrasound and needle procedures will be performed on training models, ensuring that there are no physical side effects or risks to the participants.

The following content outlines the detailed procedures of the study and important information you should be aware of. Please make sure to read it carefully.

1. Background of the Study：

Point-of-Care Ultrasound (POCUS) has gained increasing popularity in emergency medicine education in recent years. Beyond traditional physical examination tools such as stethoscopes, percussion hammers, and penlights, ultrasound has gradually become an essential component in clinical assessments. Proper ultrasound training can significantly enhance clinical decision-making and diagnostic accuracy. However, ultrasound education faces challenges due to

limited access to ultrasound machines, a shortage of clinical instructors, and a large number of learners. These factors result in fewer opportunities for hands-on practice, thereby affecting the quality of training. A key issue in improving training quality lies in how to effectively transfer ultrasound procedural skills to learners through hands-on learning experiences.

A randomized controlled study published in *BMC Medical Education* in 2020 explored the role of video resources and peer-assisted learning in ultrasound education for medical students. Typically, ultrasound training is supervised by experienced faculty through bedside instruction or peer practice. However, with large numbers of participants, one-on-one instruction by faculty becomes impractical. To overcome this, the use of instructional videos—along with peer-led sessions conducted by trained learners—has been proven both feasible and effective. Nonetheless, that particular study focused on using ultrasound for diagnostic purposes in abdominal and cardiac assessments. To date, there is limited research examining how instructional videos influence training for **ultrasound-guided invasive procedures**.

There is also growing interest in the optimal filming approach for procedural training videos. First-person point-of-view (POV) filming has been proposed as a method to increase realism and enhance learning. For example, in the UK, medical schools have employed GoPro cameras to film clinical rounds, handovers, and patient communication from a first-person perspective. This immersive and reproducible teaching method offers a scalable alternative to traditional small-group simulation training, requiring fewer resources and less time.In nursing education, research published in the fields of cognitive learning and experimental psychology examined skill acquisition through different video perspectives. Participants were randomly assigned to one of three video conditions:Face-to-face (frontal) view, Over-the-shoulder (downward) view, Mixed view (alternating between frontal and shoulder-down perspectives for each step). A fourth group served as the control and did not view any videos. The study found that learners in the mixed-view group performed significantly better than those in the other groups. While both the face-to-face and shoulder-down groups outperformed the control group, there was no significant difference between the two. Furthermore, learners in the mixed-view group reported the highest confidence in their ability to perform the procedures safely and accurately.

2.Purpose of the Study/Trial

Planned Number of Participants: 72 (Total: 72 participants, all based in Taiwan)
Purpose of the Study/Trial: (i)Primary Objective: To evaluate the effectiveness of pre-course instructional videos in enhancing the learning outcomes of ultrasound education—specifically by comparing participants who viewed the videos before the session with those in the control group who did not.(ii) Secondary Objective: To investigate the impact of different video filming perspectives—first-person point-of-view (POV) versus face-to-face filming—on the learning effectiveness in ultrasound skills training.

3.Main Inclusion and Exclusion Criteria of the Study/Trial

(1) Inclusion Criteria (Conditions for Participation): Physicians in Postgraduate Year (PGY) training and medical students at this hospital who voluntarily register and agree to participate in the study.
(2) Exclusion Criteria (Conditions Preventing Participation): None.

4. Study/Trial Methodology

Physicians at our hospital with a strong interest in learning ultrasound-guided central venous catheter (CVC) insertion in emergency settings were recruited and randomly assigned, based on a random number table, into one of three groups: (1) the POV first-person instructional video group, (2) the face-to-face side-view instructional video group, and (3) the control group that did not watch any video before the training. Participants in the video groups received an email containing the instructional video one week before the training, while the control group received a standard pre-class reminder email.

Three types of questionnaires were used in this study (pre-training questionnaire, skills checklist, and post-training questionnaire), each taking approximately 10 minutes to complete. On the training day, participants first completed the pre-training questionnaire, which included questions on demographics, self-assessment of prior procedural experience, and whether they had watched the pre-class video. Immediately afterward, participants underwent a pre-training practical test, performing CVC on a phantom model under ultrasound guidance. Their performance was recorded on video, and instructors assessed their skills using the standardized checklist.

This was followed by one-on-one instruction, during which the instructors provided detailed guidance on each procedural step. Participants then completed a full post-training practical test, performing the CVC procedure independently. Their performance was again assessed using the skills checklist as the outcome measure. After the hands-on training, participants completed the post-training questionnaire, which evaluated their satisfaction and self-confidence in performing the procedure.

5. Possible side effects, occurrence rates, and handling methods:

This teaching program will use one-on-one standardized instruction during the on-site teaching period. The students will not lose any learning benefits, and the scores for this case skill assessment will not affect the students' daily evaluations. The relevant data will not be used as a reference for the teaching department's grading. Additionally, both the ultrasound and needles used in this case will be applied on molds, so there will be no adverse physical side effects on the students. If there are any dissatisfaction with the teaching activity design, the teacher will communicate with the students and make necessary adjustments.

6. Other possible treatment methods and explanations:

Not applicable.

7. Expected outcomes of the trial/research:

Previous literature on "Ultrasound operation as a diagnostic tool for abdominal and cardiac diseases training" has confirmed that using instructional videos, combined with peer teaching conducted by trained students acting as instructors, has been proven to be feasible and effective. Additionally, nursing education literature has shown that learners who watched instructional videos performed better in pre- and post-tests compared to the control group who did not watch the videos.

This trial is based on the aforementioned literature, with the objective of teaching "ultrasound-guided central venous catheter operation." The trial will compare pre- and post-test results between groups using different perspective videos and a control group that did not watch the videos, aiming to enhance teaching quality and improve the learning outcomes of the students.

8. Requirements for participants during the trial/research:
Read the pre-course instructional videos and complete the questionnaire.

9. Confidentiality:
Taipei Veterans General Hospital will treat any records that can identify your identity and personal privacy information as confidential and will not disclose them. The researchers will assign a research code to represent your identity, and this code will not include identifiable information such as your name, national identification number, address, etc. If the trial results are published, your identity will remain confidential. You also understand that by signing the consent form, you agree that your original learning records may be directly reviewed by monitors, auditors, the Taipei Veterans General Hospital Human Research Ethics Committee, and regulatory authorities, to ensure that the clinical trial process and data comply with relevant laws and regulations. The aforementioned personnel are committed to maintaining the confidentiality of your identity. Aside from the aforementioned institutions that are legally authorized to review your information, we will take great care in safeguarding your privacy.

10. Compensation for Damages and Insurance:
(1) If adverse reactions or injuries occur as a result of this trial/research according to the clinical trial plan, Taipei Veterans General Hospital will be responsible for compensation. However, adverse reactions that are predictable as described in the participant consent form will not be compensated.
(2) If adverse reactions or damages occur as a result of this trial/research according to the clinical trial plan, Taipei Veterans General Hospital is willing to provide professional medical care and consultation.
(3) Apart from the compensation and medical care mentioned in the previous two points, this trial/research does not provide other forms of compensation or indemnity. If you are not willing to accept these risks, please do not participate in the trial.
(4) Signing this consent form will not deprive you of any legal rights.
(5) This trial/research is not insured under human trial liability insurance.

If you suffer damages due to adverse reactions caused by participating in this trial/research, the compensation mentioned above includes reasonable medical

expenses, provided the following conditions are met: the damage was not intentionally caused, and you followed the trial physician's recommendations.

11. Who can use your specimens and data:
According to the "Human Research Act," only the principal investigator, co-investigators, and the personnel involved in the study may use your trial/research data during the course of the trial/research in accordance with the clinical trial plan. If the data needs to be used after the trial/research ends, a separate consent form will be required by law.

12. Handling and storage methods of specimens and data after the trial/research ends:
Data retention, use, and reuse:
During the trial/research, based on the type of trial and the content you have authorized, we will collect data and information related to you, such as pre- and post-test questionnaires, skill checklists, etc., and substitute your name and personal information with a trial number (de-identified). If the data is in paper form, it will be stored separately from this consent form in a locked cabinet at the trial/research institution. If stored electronically for statistical and analytical purposes, it will be saved on a dedicated computer equipped with passwords and appropriate antivirus software. The principal investigator, Dr. Liao Bo-Xiang, will be responsible for keeping the data for three years.

13.Withdrawal and Termination of the Trial/Research and Handling of Specimens and Data:
You are free to decide whether to participate in this trial/research. You may withdraw your consent and exit the trial at any time during the research process, without needing to provide any reason. This will not result in any unpleasant consequences or affect your future evaluations by your physician, clinical guidance, or teaching.
If important new information arises during the course of the trial/research (that is related to your interests or might affect your willingness to continue participating), you will be notified and further explained to you. You can then reconsider whether to continue, and you are free to make your decision. This will not result in any unpleasant consequences or affect your future evaluations by your physician, clinical guidance, or teaching.

The principal investigator, Dr. Liao Bo-Xiang, may also decide to terminate the trial/research if necessary, which will not affect your career or promotions as a PGY doctor.

When you withdraw from the trial/research or the principal investigator determines that you are not suitable to continue, the data obtained before your withdrawal will be retained and not removed. After your withdrawal, the trial/research team will no longer collect your data.

14. If the results of this trial/research are published in academic literature or lead to intellectual property or tangible benefits, Taipei Veterans General Hospital will use them in accordance with the law for medical purposes such as disease diagnosis, prevention, treatment, and research.

15. Rights and Obligations of Participants:

(1) You are not required to pay any fees to participate in this trial/research.

(2) This trial/research does not offer any subsidies or gifts.

(3) This trial/research is not covered by the National Health Insurance. All costs related to the trial/research will be borne by this project.

(4) Any significant findings during the trial/research that may affect your willingness to continue participating, especially those related to your health or illness, will be provided to you immediately. If you decide to withdraw, the physician will arrange for you to continue receiving medical care.

(5) If you have any questions about the nature of the study/trial, concerns about your rights as a participant, or believe you may have been harmed as a result of participation in the study/trial, you may contact the Institutional Review Board (IRB) of our hospital for consultation. The phone number is: (02) 2875-7384.

(6) In order to carry out the trial/research, you must receive care from the principal investigator. If you have any questions or issues now or during the trial, please feel free to contact Dr. Liao Bo-Xiang at the Emergency Department of Taipei Veterans General Hospital (24-hour contact number: 0958516762).

(7) This consent form is made in duplicate. The principal investigator has provided you with a copy of the consent form and has fully explained the nature and purpose of this trial/research. Dr. Liao Bo-Xiang from the Emergency Department has answered all your questions regarding the trial/research.

16. Signature

(1) The principal investigator or co-investigator guarantees that either I, or a member of my trial/research team (who has been authorized to perform this step), has explained the above details regarding this trial/research, including its purpose, procedures, potential risks and benefits related to participation, and available alternative treatments. All questions raised by the participant have been answered.

Principal Investigator / Co-investigator:_____(Signature)

Date:____Year____Month____Day (Please make sure to fill in)

Other research personnel involved in the explanation and discussion during the consent process:_____(Signature)

Date:____Year____Month____Day (Please make sure to fill in)

(2) The participant has fully understood the trial/research methods described above, along with the potential risks and benefits. Any questions regarding this trial plan have been thoroughly explained by the principal investigator. I agree to voluntarily participate as a subject in this clinical trial plan.

Participant:_____(Signature)

Date:____Year____Month____Day (Please make sure to fill in)

Note 1: This consent form applies to adults aged 18 and above, and the participant must sign it personally, with the date clearly stated, for it to be valid.

Note 2: If the participant is unable to read the above content and it is explained orally by the researcher, a legal guardian, caregiver, or someone with consent authority must be present.