An Augmented Reality-Based Guide for Mechanical Ventilator Setup: Prospective Randomized Pilot Trial

Aim of the Study
The aim of this study was to determine the feasibility and effectiveness of augmented reality (AR)-based self-learning for novices to set up a ventilator without on-site assistance. This was a prospective randomized controlled pilot study conducted at Samsung Medical Center, Korea, from January to February 2022. Nurses with no prior experience of MV or AR were enrolled. "We randomized the participants into two groups: manual and AR groups. Participants in the manual group used a printed manual and made a phone call for assistance, whereas participants in the AR group were guided by AR-based instructions and requested assistance with the head-mounted device (HMD)." We compared the overall score of the procedure, required level of assistance, and user experience between the groups.

Methods
Participants in the AR group were provided 15 minutes of learning and practice time with the HoloLens 2. If they needed assistance, the participants in the AR group requested it remotely with HoloLens 2; subsequently both groups were assisted by the same ICU nurse. In the AR group, the participants shared the same view as the nurse utilizing the dynamic 365 Guide (Software, Microsoft Corporation, Redmond, WA, USA), which allowed the ICU nurse to guide the participants through voice commands and by drawing marks on their view. The instructions detailed the entire process, from plugging in a socket to turning on the power by performing initial ventilator administration. Beginners may find it easier to learn through a voice and visual guide.

Results
We compared two modes of training, namely, the conventional method (printed manual) and AR-based instructions. Participants in the AR group made less mistakes and required less assistance than those in the manual group. The AR group’s average score was higher than the manual group's. The study demonstrated the feasibility and effectiveness of AR-based self-learning for novices to set up a ventilator.
5-i) Describe use parameters
The study was regarding to nursing education, subitem 5-x was not indicated.

5-ii) Report any prompts/reminders used
In this study, only Hololens 2 was used for intervention, so the other co-intervention was not existed.

6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
All the continuous variables are described as mean ± SD and median (IQR) and categorical variables as n (%). For continuous variables, we used the Wilcoxon rank-sum test; for categorical values, we used the chi-square test or Fisher’s exact test. A proportion test was performed to compare the proportions between the two groups. For all statistical analyses, a P-value<.05 was considered as statistically significant. The statistical analysis was performed using the R software (version 4.1.2, R Foundation for Statistical Computing, Vienna, Austria).

7a) CONSORT: Blinding - If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
Nothing of them was blinded.

8a) CONSORT: Method used to generate the random allocation sequence
The participants were randomly assigned to two groups using a lottery method.

8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)
The participants were randomly assigned to two groups using a lottery method. One group (manual group) used a printed manual to set up a ventilator and the other group (AR group) used AR-based instructions through a HMD Hololens 2 (Microsoft Corporation, Redmond, WA, USA).

9) CONSORT: Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
The participants were randomly assigned to two groups using a lottery method.

10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
KM generated a draw, H-SJ enrolled participants, and we assigned participants as a result of lottery method.

11a) CONSORT: Blinding - If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
11a-i) Specify who was blinded, and who wasn’t
Nothing of them was blinded.

11b) CONSORT: If relevant, description of the similarity of interventions

12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes
The participants were randomly assigned to two groups using a lottery method.

12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses
We did not conduct additional analyses.

RESULTS

13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
All 30 participants completed the entire procedure, with or without remote assistance.

13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons
A total of 31 nurses with no prior experience in setting up ventilators were enrolled.

13b-i) Attrition diagram

14a) CONSORT: Dates defining the periods of recruitment and follow-up

14b) CONSORT: Why the trial ended or was stopped (early)

15) CONSORT: A table showing baseline demographic and clinical characteristics for each group
We described the participant's demographics in Table 1.

15-i) Report demographics associated with digital divide issues
We described the participant's demographics in Table 1.

16a) CONSORT: For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple "denominators" and provide definitions
The item is not applicable/relevant for our study: because the study objective is nursing education

16-ii) Primary analysis should be intent-to-treat

17a) CONSORT: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
We described the overall outcomes in Table 2.

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended
We described the overall outcomes in Table 2.

18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
The item is not applicable/relevant for our study.

19) CONSORT: All important harms or unintended effects in each group
The item is not applicable/relevant for our study because the study objective was nursing education.

19-i) Include privacy breaches, technical problems

19-ii) Include qualitative feedback from participants or observations from staff/researchers

DISCUSSION

20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses

20-i) Typical limitations in ehealth trials

As a pilot study, there was no specific guideline regarding how to deal with technology issues, such as time for battery charging, overheating of the device without break time, and network instability. These issues were observed in a few cases but were solved without affecting the study; however, these issues will be addressed and planned in a larger scale study. Additionally, in the step-by-step procedures, the content of the errors is important; however, this was not addressed in this study. To extend AR-based training in other step-by-step advanced procedures and explore additional outcomes, considering the characteristics of steps and designing a training platform for suitable technology integration would be required.

21) CONSORT: Generalisability (external validity, applicability) of the trial findings

21-i) Generalizability to other populations

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

22) CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

In this study, the participants had no prior experience with the ventilator setup or AR HMD; additionally, all novices completed the entire procedure, from preparing materials to setting up the initial ventilator mode prior to connecting to the patient. Moreover, the AR group was able to complete all the procedures following AR-based instructions in the planned design of the study, including a brief AR HMD practice and self-learning session. They required significantly lesser assistance than the manual group, and all assistance could be provided properly through remote AR systems. There were no technical issues or dropouts in either group.

22-ii) Highlight unanswered new questions, suggest future research

Other information

23) CONSORT: Registration number and name of trial registry

ClinicalTrials.gov ID: NCT05446896

24) CONSORT: Where the full trial protocol can be accessed, if available

We registered the study at ClinicalTrials.gov

25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders

This study was not funded

X26-i) Comment on ethics committee approval

X26-ii) Outline informed consent procedures

X26-iii) Safety and security procedures

X27-i) State the relation of the study team towards the system being evaluated