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Major articles

Randomized, controlled trial of the effectiveness of simulation education: A 24-month follow-up study in a clinical setting

Miia M. Jansson PhD [a,b,c,*], Hannu P. Syrjälä MD, PhD [c,d], Pasi P. Ohtonen MSc (Statistics) [e], Merja H. Meriläinen PhD [a,c], Helvi A. Kyngäs PhD [b,c,f], Tero I. Ala-Kokko MD, PhD [a,c]

[a] *Division of Intensive Care, Department of Anesthesiology, Oulu University Hospital, Oulu, Finland*
[b] *Institute of Health Science, University of Oulu, Oulu, Finland*
[c] *Medical Research Center Oulu, Oulu, Finland*
[d] *Department of Infection Control, Oulu University Hospital, Oulu, Finland*
[e] *Department of Anesthesiology, Oulu University Hospital, Oulu, Finland*
[f] *Northern Ostrobothnia Hospital District, Oulu, Finland*

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Background: Critical care nurses' knowledge and skills in adhering to evidence-based guidelines for avoiding complications associated with intubation and mechanical ventilation are currently limited. We hypothesized that single simulation education session would lead to a long-lasting higher level of skills among critical care nurses.

Material and methods: A randomized controlled trial was conducted in a 22-bed adult mixed medical-surgical intensive care unit in Finland during the period February 2012-March 2014. Thirty out of 40 initially randomized critical care nurses participated in a 24-month follow-up study. Behavior and cognitive development was evaluated through a validated Ventilator Bundle Observation Schedule and Questionnaire at the baseline measurement and repeated 3 times during simulation and real-life clinic settings.

Results: After simulation education, the average skills score increased from 46.8%-58.8% of the total score in the final postintervention measurement ($P_{time} < .001$, $P_{time \times group} = .040$, and $P_{group} = .11$). The average knowledge scores within groups did not change significantly. The average between-group difference in skills scores was significant only at the measurement taken at 6 months ($P = .006$).

Conclusions: Critical care nurses' skills in adhering to evidence-based guidelines improved in both groups over time, but the improvements between the study groups was significantly different only at 6 months and was no longer evident after 2 years following a single simulation education.

Professional practice in high-risk critical care settings requires specialized knowledge and advanced skills to assess, monitor, and effectively respond to the needs of critically ill patients.[1,2] However, critical care nurses' theoretical and applied knowledge has been limited.[3] In addition, critical care nurses' skills in adhering to evidence-based guidelines for avoiding complications associated with intubation and mechanical ventilation have been limited.[4]

Advanced, high-fidelity teaching methods that require participants to behave as they would in real life have been associated with improved learning and clinical outcomes.[5] Generally in nursing education, high-fidelity simulation using a computerized full-body mannequin has been an effective teaching and learning method when best practice guidelines are followed.[6,7]

Previous single-center, prospective, parallel, controlled,[8-11] and cohort[12] studies have demonstrated significant improvements in participants' cognitive, behavioral, and psychomotor skills as well as clinical outcomes after simulation education: During the study periods, medication administration error rates have decreased from 30.8%-6.2% ($P < .001$)[10] and the incidence of catheter-related bloodstream infections has decreased from 2.61-0.4 infections per 1,000 catheter days ($P = .02$).[11] However, the longitudinal effects of simulation education are still largely unknown. For example, the previous short- and long-term effects have been evaluated at baseline

* Address correspondence to Miia M. Jansson, PhD, Institute of Health Sciences, University of Oulu, Box 5000, Oulu 90014, Finland.
E-mail address: miia.jansson@oulu.fi (M.M. Jansson).

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measurement and repeated immediately or 1-12 weeks to 3-12 months postintervention.[8-14]

In our previous prospective, parallel, randomized controlled trial, we identified a significant transfer of learned skills to clinical practice following simulation education and an improvement that was still evident after 6 months of follow-up.[14] The aim of the present trial was to evaluate the longitudinal effects of simulation education in the nursing management of patients receiving invasive ventilation. The primary and secondary outcomes measured were critical care nurses' knowledge and skills in adhering to an expanded ventilator bundle (VB) (a package of evidence-based guidelines to prevent adverse events in ventilated patients, including ventilator-associated pneumonia [VAP]), compared between randomly allocated intervention and control groups before and 24 months after an education-based intervention. It was hypothesized that the participants who received verbal feedback and participated in structured debriefing focusing on the expanded VB would demonstrate a higher level of skill than those who did not receive the simulation education.

MATERIALS AND METHODS

Study design

This study was designed as a longitudinal, single-center, parallel, randomized controlled trial with repeated measurement. The reporting of this study complies with the Consolidated Standards of Reporting Trials statement for trials of nonpharmacologic treatments.[15]

Sample and setting

The study was conducted in a single academic center among critical care nurses in a 22-bed adult mixed medical-surgical intensive care unit in Finland from February 2012-March 2014. A sample size was calculated to detect 20% difference between the study groups in the average skill score ($\alpha = 0.05$, $1\text{-}\beta = 90\%$, and dropout level = 20%). Participants were allocated to the intervention (n = 20) or control group (n = 20) separately in 2 age-based strata, according to a computer-generated randomization list.[14] Previously recruited participants (registered nurses who were direct care providers) were asked to participate in the extension study via e-mail.[14] Written informed consent from participants was obtained before inclusion in the study (Declaration of Helsinki 2013). According to the Medical Research Act (488/1999 and amendments 295/2004), approval of the local ethics committee was not required for studies focusing on health care staff, whereas the study protocol was reapproved by the relevant academic center during fall 2013.

Intervention and study protocol

The high-fidelity, human patient simulation education process began with a brief (20 minutes) introduction to the simulation center (SimLab; Oulu University of Applied Science, Oulu, Finland) and mannequin (HAL; Gaumard, Miami, FL) followed by an actual simulated scenario (10 minutes) in which participants were asked to do all of the essential nursing interventions aimed at preventing VAP. Only the intervention group received verbal feedback and participated in structured debriefing (60 minutes) focusing on the expanded VB (Fig 1).

The baseline (initially before the intervention) and initial postintervention (3 months after the intervention) measurements were conducted in a simulation setting (follow-up I).[14] The final postintervention measurements (6 and 24 months after the intervention) were made in a real-life clinic setting (follow-up II and III) during the morning shift in our adult mixed medical-surgical intensive care unit. Identical measurements were taken for the study groups by the same trained and experienced observers who also performed the primary evaluations.

Critical care nurses' skills were evaluated while managing care for adult patients receiving invasive ventilation using a direct, nonparticipatory method of observation. The method was guided by a validated (S-CVI 0.99), highly structured 86-item (Fig 1) Ventilator Bundle Observation Schedule (VBOS). If participants adhered to a recommended practice, they were assigned 1 point, yielding a skill score range of 0-60.[16]

The intraclass correlation coefficient, including 95% confidence interval, and the Cohen kappa coefficient of each item and the average scale score (ie, VBOS) were tested using a second observer during data collection. The interclass coefficient of the average scale score was 0.99 (95% confidence interval, 0.98-1.0). In addition, the kappa value of each item varied from $\kappa = 0.25$ to $\kappa = 1.0$, demonstrating fair to perfect agreement.[17]

The level of critical care nurses' knowledge was evaluated at the end of each observation session using a validated (S-CVI 1.0) 49-item (Fig 1) Ventilator Bundle Questionnaire. The method was guided by a blinded research assistant, who arranged an appropriate time and venue to gather the responses. If participants answered correctly, they scored 1 point, yielding a knowledge score range from 0-37.[16]

Data analysis

The primary end point was the difference in the skill scores between the baseline measurement and 24 months after the intervention compared between randomly allocated intervention and control groups. Secondary end points were represented by the change in knowledge scores. The statistical analysis was performed using SPSS version 18.0 for Windows (IBM-SPSS Inc, Armonk, NY) or SAS (version 9.3; SAS Institute Inc, Cary, NC). The repeatedly measured data were analyzed using a linear mixed model with a covariance pattern model (continuous variables). Age was added as a covariate if necessary (ie, P value for age < .05). P values reported for repeatedly measured data are as follows: P-time (P_t), the overall change over time; P-group (P_g), the average between-group difference; and P-time × group ($P_{t \times g}$), the interaction between time and group. All participants were included in the groups to which they were originally assigned (intention-to-treat analysis). A 2-tailed P value < .05 was considered statistically significant.

RESULTS

Thirty out of 40 initially randomized critical care nurses participated in a 24-month follow-up study, of whom 17 completed all the study procedures (Fig 2). The majority of participants were female (70.0%), often held a bachelor's degree (96.7%), were permanently employed (66.7%), and had less than 5 years of work experience (53.3%). The withdrawal rate between the study groups varied from 26.7% (intervention group) to 60.0% (control group). Following the baseline measurement, the reasons for withdrawal in the intervention group were sudden illness (n = 1), job transfer (n = 1), declining to participate (n = 1), and not known (n = 1). The main reasons for withdrawal in the control group were declining to participate (n = 3), sudden illness (n = 2), job transfer (n = 2), and other reason (n = 2).