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

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Conflict of interest

No conflict of interest has been declared by the authors.

Author contributions

M.M.J., H.P.S., P.P.O., M.H.M., H.A.K., and T.I.A.-K. contributed to the study design. M.M.J. contributed to data collection. M.M.J. and P.P.O. performed the data analysis. M.M.J., H.P.S., P.P.O., M.H.M., H.A.K., and T.I.A.-K. contributed to data interpretation and manuscript preparation.

ABSTRACT

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 from February 2012 to March 2014. Thirty out of forty initially randomized critical care nurses participated in a 24-month follow-up study. Behavioral and cognitive development was evaluated through a validated Ventilator Bundle Observation Schedule and Questionnaire at the baseline measurement and repeated three times during simulation and real-life clinical settings.

Results: After simulation education, the average skills score increased from 46.8% to 58.8% of the total score in the final post-intervention measurement ($p_t < 0.001$, $p_{t*g} = 0.040$, $p_g = 0.11$). The average knowledge scores within either group did not change statistically significantly. The average between-group difference in skills scores was significant only at the six months measurement ($p = 0.006$).

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 six months and was no longer evident after two years following a single simulation education.

Keywords: Critical care, Nursing education, Knowledge, Simulation, Skills, Mechanical ventilation

BACKROUND

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 the participants to behave as they would behave 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% to 6.2% ($p < 0.001$) [10] and the incidence of catheter-related bloodstream infections has decreased from 2.61 to 0.4 infections per 1000 catheter-days ($p = 0.02$).[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 measurement and repeated immediately or 1–12 weeks to 3–12 months post-intervention. [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 six 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 invasively ventilated patients. 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), compared between randomly allocated intervention and control groups before and 24 months after educational 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.

MATERIAL AND METHODS

Study design

This study was designed as a longitudinal, single-center, parallel, randomized controlled trial (RCT) with repeated measurement. The reporting of this study complies with the CONSORT (Consolidated Standards of Reporting Trials) statement for trials of non-pharmacological 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 ICU in Finland from February 2012 to March 2014. A sample size was calculated to detect 20% difference between the study groups in the average skill score (α = 0.05, 1-β = 90%, dropout level = 20%). Participants were allocated to the intervention (n = 20) or control group (n = 20) separately in two 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 email. [14] Written informed consent from participants was obtained prior to 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 healthcare staff while the study protocol was re-approved by the relevant academic center in 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) 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 ventilator-associated pneumonia (VAP). Only the intervention group received verbal feedback and participated in structured debriefing (60 minutes) focusing on the expanded VB (Figure 1).

The baseline (initially before the intervention) and initial post-intervention (3 months after the intervention) measurements were conducted in a simulation setting (follow-up I).[14] The final post-intervention measurements (6 and 24 months after the intervention) were made in a real-life clinical setting (follow-up II and III) during the morning shift in our adult mixed medical-surgical ICU. 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 adult, invasively ventilated patients using a direct, non-participatory method of observation. The method was guided by a validated (S-CVI 0.99), highly structured 86-item (Figure 1) Ventilator Bundle Observation Schedule (VBOS). If participants adhered to a recommended practice, they were assigned one point, yielding a skill score range from 0 to 60. [16]

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

The level of critical care nurses' knowledge was evaluated at the end of each observational sessions using a validated (S-CVI 1.0) 49-item (Figure 1) Ventilator Bundle Questionnaire (VBQ). 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 one point, yielding a knowledge score range from 0 to 37. [16]

Data analysis

The primary endpoint 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 endpoints were represented by the change in the knowledge scores. The statistical analysis was performed using SPSS 18.0 for Windows (SPSS INC., Chicago, IL) or SAS (version 9.3. SAS Institute Inc., Cary, NC, USA). The repeatedly measured data was analyzed using a linear mixed model with a covariance pattern model (continuous variables). Age was added as a covariate if necessary (i.e. *p*- value for age < 0.05). *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*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 two-tailed *P* value less than 0.05 was considered statistically significant.

RESULTS

Thirty out of forty initially randomized critical care nurses participated in a 24-month follow-up study, of whom seventeen completed all the study procedures (Figure 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 five years working experience (53.3%). The withdrawal rate between the study groups varied from 26.7% (intervention group) to 60.0% (control group). Following to 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).

Critical care nurses' skills in adhering to evidence-based guidelines before and after simulation education

After simulation education, the average skill score (VBOS) increased from 46.8% to 58.8% (intervention group) and from 48.8% to 59.7% (control group) of the total score in the final post-intervention measurement ($p_t < 0.001$, $p_{t*g} = 0.040$, $p_g = 0.11$). The average between-group difference in skill score was significant only at the six month measurement (4.6 points, 95% CI 1.4 to 7.9, $p = 0.006$). (Figure 3.)

In the baseline measurement, 33.3% (intervention group) compared to 13.3% (control group) of participants achieved a mean score of 50%. However, in the final post-intervention measurement, a low of 33.3% (control group) to a high of 90.0% (intervention group) of participants achieved it. The median delta skill score (baseline-final post-intervention measurement) was 7.1 (25^{th}–75^{th} pct. 4.5–10.0) in the intervention group compared to 6.5 (25^{th}–75^{th} pct. 3.0–10.0) in the control group ($p = 0.83$).

Critical care nurses' knowledge of evidence-based guidelines before and after simulation education

After simulation education, the average knowledge score (VBQ) increased from 58.6% to 63.8% (intervention group) and from 50.3% to 55.4% (control group) of the total score in the final post-intervention measurement ($p_t = 0.36$, $pt*g$ <0.001, $p_g > 0.9$). (Figure 4.) In the baseline measurement, 73.3% (intervention group) compared to 13.3% (control group) of participants achieved a mean score of 50%. However, in the final post-intervention measurement, a low of

20.0% (control group) to a high of 60.0% (intervention group) of participants achieved it. The median delta knowledge score (baseline-final post-intervention measurement) was 1.1 (25^{th}–75^{th} pct. 0–3.0) in the intervention group compared to 1.5 (25^{th}–75^{th} pct. -3.0–3.0) in the control group ($p = 0.85$).

DISCUSSION

This is the first 24-month longitudinal RCT with repeated measurement to evaluate the effectiveness of a single high-fidelity simulation education in infection control on nursing continuing education. [18 – 19] Contrary to previous studies, the longitudinal effects (e.g., knowledge and skills) were assessed both in simulation and real-life clinical settings. The skill scores improved in both group over time, but the improvement between study groups was significantly different only at six months.

During the study period, the average skill and median delta skill scores in the intervention group increased only by 12 percentage points. In the baseline measurement, interestingly, only 33.3% of the intervention group achieved a mean score of 50%. In the final post-intervention measurement, however, 90.0% of them achieved it. According to our findings, however, critical care nurses' adherence to the expanded VB remained below targeted behavior rates, leaving room for improvement; according to Pogorzelska *et al*., adherence should be at least 95% before the incidence of VAP will decrease. According to different estimates, however, approximately 55% of cases of VAP could be prevented through intensive infection control programs. [21] Traditionally, these programs are presented in the form of a didactic lecture in conjunction with other complementary interventions; however most of the effects have remained small to moderate and often short-term because education alone is usually insufficient to change healthcare practitioners' behaviors permanently

Simulation education may have some advantages over other teaching methods (including traditional didactic lecture or video training alone) [8, 10, 22], depending on the context, topic and method. [6] Previous studies have demonstrated more long-lasting improvements in learning (e.g., cognitive, behavioral and psychomotor skills) and clinical outcomes (e.g., incidence of ICU acquired infections, medication errors) after regularly repeated educational sessions (including immediate audiovisual debriefing and feedback, retraining and reassessment) indicating that these approaches would provide more long-lasting improvements than a single verbal debriefing without the retraining possibilities used in this trial. [6, 8 – 13]

The variability of findings among the published studies might result from the lack of robust evidence (including variations in the research designs) and of a universal method for outcome measurement (e.g., a constructivist vs. behaviorist approach in designing learning and assessment, and a lack of standardized instruments, measurements and follow-up times). Contrary to traditional teaching methods, the components of concrete experimentation, combined with audiovisual and immediate expert constructive debriefing and feedback (reflective observation, abstract conceptualization) with retraining possibilities (active experimentation) are based on the principles of experimental learning, which are particularly suited to nurses' continuing education, where integration of theory and practice is essential and ongoing. [23] It must be noted, however, the effectiveness of simulation education compared with other educational interventions is difficult to assess due to a lack of robust evidence and a universal method of outcome measurement.

The major study limitations and the potential source for bias are related to internal and external validity. The lack of significant enhancement of participant knowledge may have been attributable to the limited sample size or an unreliable instrument. The withdrawal rate was higher in the control group compared to the intervention group. One reason for a lack of significant difference between the study groups in the final post-intervention measurement may be due to drop out of the participants in the control group with the lowest scores at the six-month follow-up (data not shown). In addition, a single-center study limits generalizability; the results may not be applicable to different populations, setting or situations.

In the future, there will be a need for blinded, randomized controlled follow-up studies to explore the relationship between simulation education and clinical outcomes. In addition, there is a need for continuous, multimodal and multidisciplinary interventions, which have been more effective than a single educational intervention in terms of changing health care practitioner's behaviors related to infection control. [24, 25] Moreover, an optimal booster should be developed and investigated to enhance long-lasting behavioral changes.

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 six months and disappeared up to two years following a single simulation education.

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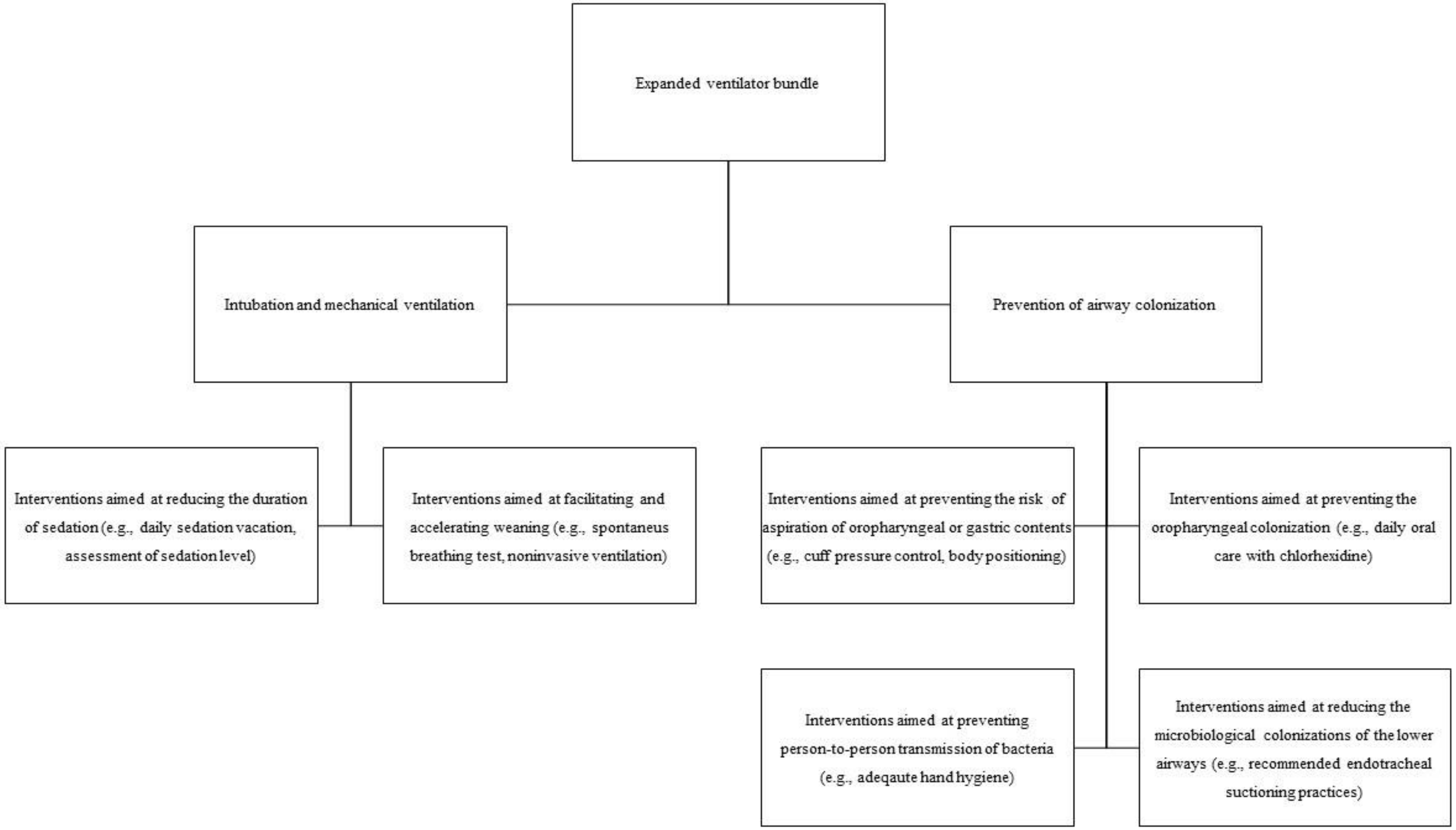

Figure 1. The content of the intervention and validated assessment tools consisted of an expanded ventilator bundle (a package of evidence-based guidelines to prevent ventilator-associated pneumonia).

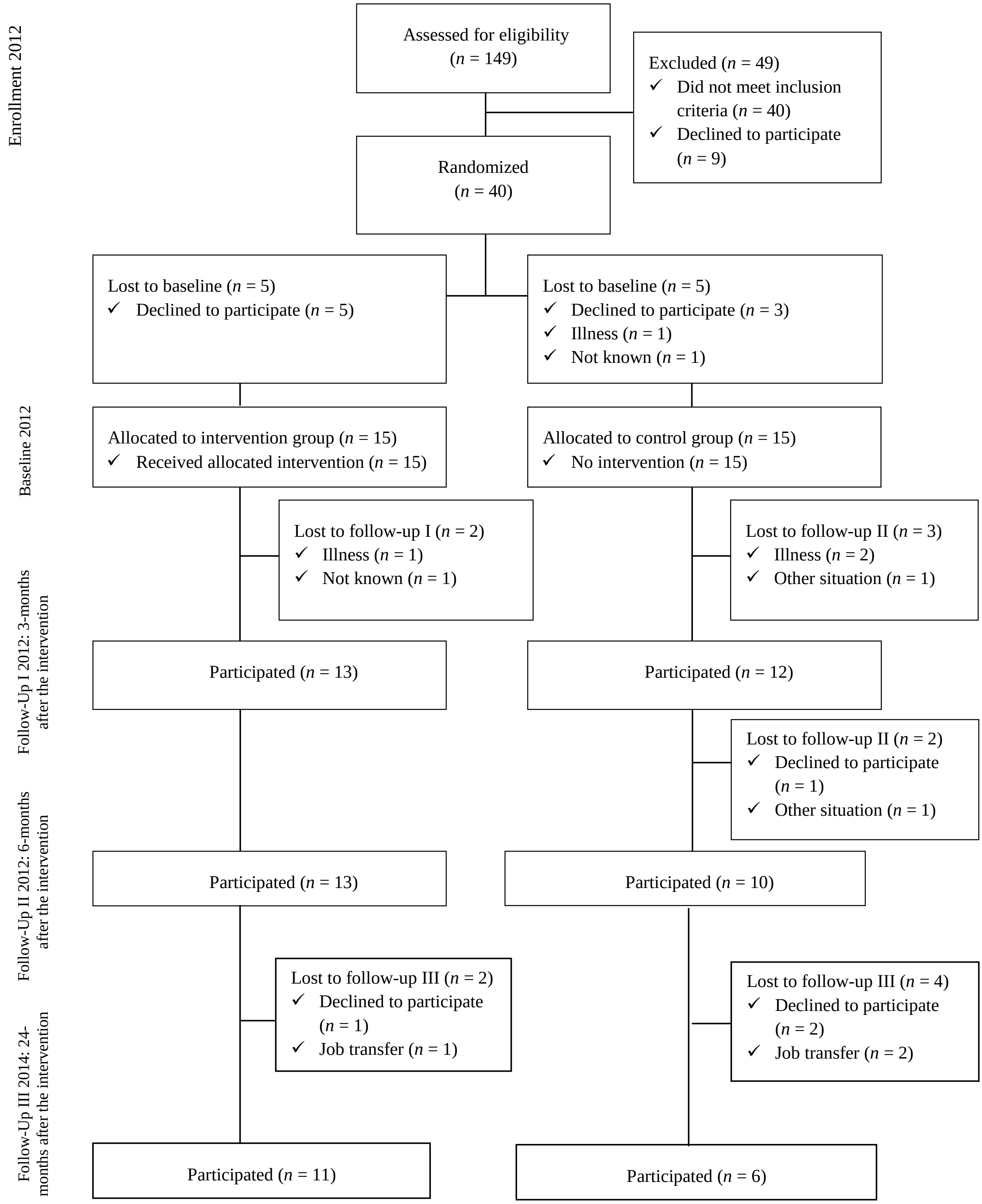

Figure 2. Flow chart of the progress through the 24-month follow-up study of a parallel randomized trial of two groups. The flow chart up to follow-up 2012 has been earlier published in the American Journal of Infection Control 2014; 42: 271–6.

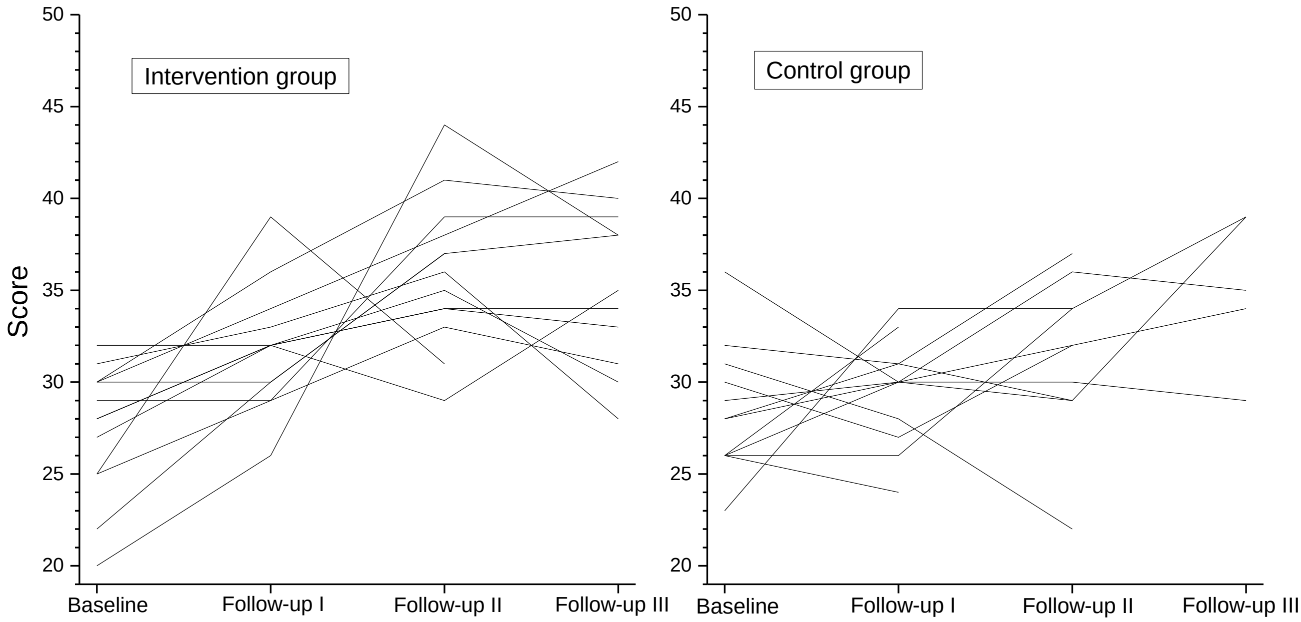

Figure 3. Critical care nurses' individual skills scores before and after simulation education ($p_t < 0.001$, $p_{t*g} = 0.040$, $p_g = 0.11$). The baseline and initial post-intervention measurements (three months after the intervention) were conducted in the simulation environment (follow-up I). The final post-intervention measurements were made at six months (follow-up II) and 24 months (follow-up III) after the intervention during the morning shift (7 AM–3 PM) in clinical practice. Note. Figures include only participants that had at least two measurement times.

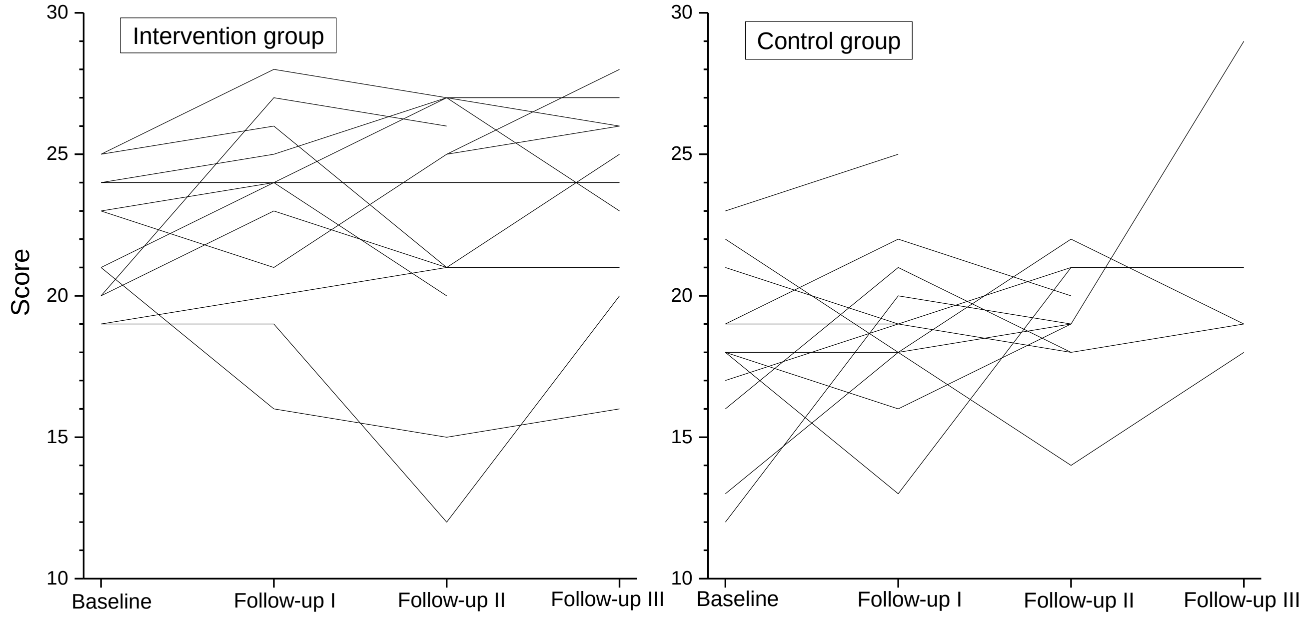

Figure 4. Critical care nurses' individual knowledge scores before and after simulation education (p_t = 0.36, *pt**g <0.001, p_g > 0.9). The baseline and initial post-intervention measurements (three months after the intervention) were conducted in the simulation environment (follow-up I). The final post-intervention measurements were made at six months (follow-up II) and 24 months (follow-up III) after the intervention during the morning shift (7 AM–3 PM) in clinical practice. Note. Figures include only participants that had at least two measurement times.