

Study Protocol and Statistical Analysis Plan

Title: Effects of Scenario-based Education Initiative and OSCE for Recognition and Management of Delirium

Protocol ID: N201803104

ClinicalTrial.gov ID: NCT05623475

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Study Protocol:

Background: Delirium is an acute change in cognitive function. More than 80% of patients develop delirium on the first day of ICU admission. Delirium increases patients' physical restraint, length of ventilator use, length of ICU stays, and mortality. Healthcare providers need to assess and provide appropriate interventions promptly.

Objective(s): To evaluate the effectiveness of the Scenario-based Education Module and Objective Structured Clinical Skills Examination (SEM-OSCE) on delirium knowledge, confidence, and competence among ICUs nurses.

Design: A cluster randomized controlled trial was conducted (IRB: N202103018).

Method:

1. The SEM-OSCE was jointly developed by the research team in Taiwan and the University of Wollongong, Australia.
2. Eligible participants were recruited from a hospital in northern Taiwan. Eligible participants were: (1) Registered nurses who worked in the acute care unit and cared for critical patients. (2) Age more than 20 years old. (3) Willing to be involved in the research.
3. Setting: A teaching hospital in northern Taiwan.
4. Intervention: The interventional group received an online delirium course, and face-to-face education using 'Delirium Care Flip Chart', and SEM-OSCE, while the control group received an online delirium course. The SEM-OSCE was jointly developed by the research team.
5. Tools: The tools included a delirium questionnaire and clinical audit. Outcome data included ICU nurses' delirium knowledge, confidence, competence, and clinical performance.
6. Data collection: Data were collected at baseline (T0), immediately after the intervention (SEM-OSCE) (T1), and 6 weeks after the intervention (SEM-OSCE) (T2).

Statistical Analysis Plan: SPSS 22.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis using descriptive analysis, t-test, Chi-Squared Test, ANOVA, and GEE.

Informed Consent Form: Reviewed by TMU-JIRB committee members, written informed consent is not required.