Assistance Publique
Hôpitaux de Marseille

Effect of a Simulation Program on the Reduction of Psychosocial Risks in ICU Nurses: a Randomized Controlled Trial
SISTRESSREA

Apport de la simulation en santé sur la gestion du stress professionnel des infirmier(e)s de réanimation

Statistical Analysis Plan

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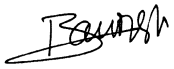

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Scientific background

- Intensive Care Unit (ICU) = stressful workplaces for nurses (occupational stressors such as: time pressure, reduced social support at work, excessive workloads, miscommunication, poor supervision, conflict with physicians, peers and patients or families, high job demands, and moral and spiritual distress related to end-of-life issues)
- The stress process results in poor individual health and less successful working, leading to professionals leaving their jobs and impacting society due to lost economic investment.
- Potential preventive action: to improve the ability of caregivers to cope with stress using Simulation
- Hypothesis: a specific training course integrating simulation techniques delivered to ICU nurses would have a positive impact on the prevention of occupational stress.

Objectives

- Primary objective: to demonstrate that a dedicated simulation education program is effective in reducing job strain evaluated at 6 months in participants compared with controls.
- Secondary objectives: to demonstrate that the program is effective on isostrain, psychosocial factors at work (including burnout assessment), nurses' absenteeism, and nurses' turnover.

Methodological aspects

- Study design: was a multicenter, randomized, 2-parallel arm, open-label, prospective study.
- Setting: 8 French adult medical, surgical and mixed ICUs.
- Participants: nurse actively working in an adult ICU, with a registered nurse's license, and at least 6 months of experience in the current ICU.
- Groups: (i) the simulation training group, which received the intervention, and (ii) the control group, which did not participate in training.
- Randomization: computer-generated randomization list (allocation ratio, 1:1), using a permuted block design, stratified on ICU and job experience (6 to 24 months vs at least 24 months).

Primary and secondary outcomes

- Job strain is evaluated using the 26-item French version of the Job Content Questionnaire (JCQ) [Karasek R, Brisson C, Kawakami N, Houtman I, Bongers P, Amick B. The Job Content Questionnaire (JCQ): an instrument for internationally comparative assessments of psychosocial job characteristics. J Occup Health Psychol. 1998;3(4):322-355]. The questionnaire covers three dimensions: psychological demand, decision latitude, and social support. According to Karasek's model, two situations are defined: job strain, which comprises a combination of high psychological demand and low decision latitude at work, and isostrain, which comprises job strain at work and low social support. The thresholds are defined from French data [Begue C, Fouquet N, Bodin J, et al. Evolution of psychosocial factors at work in a French region. Occup Med (Lond). 2016;66(2):128-134].
- Primary outcome: job strain (as defined above) at 6 months.
- Secondary outcomes: isostrain (as defined above) at 6 months; psychological demand, decision latitude and social support (from the JCQ); psychosocial factors at work (from the COPSOQ); absenteeism, defined as the proportion of ICU nurses missing at least one work day during the 6-month period following inclusion; and turnover, defined as the number of ICU nurses leaving their current positions during the 6-month period following inclusion. All these outcomes are also assessed at 12 months.

Sample size

The sample size was determined according to the prevalence of job strain in French nurses (60%) [Bellagamba G, Gionta G, Senergue J, Beque C, Lehucher-Michel MP. Organizational 416 factors impacting job strain and mental quality of life in emergency and critical care 417 units. Int J Occup Med Environ Health. 2015;28(2):357-367] through power analysis, which revealed that a sample size of 188 participants per arm was required to detect an absolute difference of 15 percentage points between the two groups (60% for the control group, 45% for the intervention group) including an interim analysis after the inclusion of 50% of the patients, with a power of 80% and a P value of 0.003 for the interim analysis and 0.05 for the final analysis (Power Analysis and Sample Size Software Version 2008, Utah, USA). Further, we anticipated a dropout rate of 12 patients per group, which led to a sample size of 200 participants per group.

Data quality

- The data collection quality is supervised by a clinical research assistant dedicated to the project.
- The database quality is supervised by the data manager (Assistance Publique - Hopitaux de Marseille).
- The database will be frozen when 50% of the participants will have reached the 6-months post-inclusion date to perform the interim analysis.

Statistical aspects

Statistical analysis of this study will be carried out in a blinded manner. The data will be analyzed using SPSS version 20.0 software (SPSS Inc., Chicago, IL). Statistical significance is defined as $P < 0.05$. The methodology will be based on the Consolidated Standards of Reporting Trials statement (CONSORT, http://www.consortstatement.org/consort-statement/) [Schulz KF, Altman DG, Moher D, et al; CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials. J Clin Epidemiol. 2010;63:834–840].

The intention-to-treat population (including all subjects who will be randomized) will be used as the primary analysis.

According to the sample size calculation, the p values are: i) for the interim analysis: 0.003; ii) for the final analysis: 0.05.

The flow chart of the study will be built including eligible participants, included participants, randomized participants, lost to follow-up (number, reasons).

The baseline parameters will be presented by group (‘control’ and ‘experimental’). The primary endpoint, proportions of job strain at 6 months (from the Job Content Questionnaire), will be compared between the 2 groups ($\chi 2$ test/ Fisher’s exact test). Proportions of isostrain, absenteeism and turnover at 6 months ($\chi 2$ test/Fisher’s exact test), the different scores of the JCQ and COPSOQ (Mann-Whitney tests) will be compared between the 2 groups. Differences in psychological demand, decision latitude and social support between the baseline and 6-month assessments will be compared between groups (Mann-Whitney tests) and within groups (Wilcoxon tests).