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Effects of a Multimodal Program Including Simulation on Job Strain Among Nurses Working in Intensive Care Units
A Randomized Clinical Trial

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IMPORTANCE Nurses working in an intensive care unit (ICU) are exposed to occupational stressors that can increase the risk of stress reactions, long-term absenteeism, and turnover.

OBJECTIVE To evaluate the effects of a program including simulation in reducing work-related stress and work-related outcomes among ICU nurses.

DESIGN, SETTING, AND PARTICIPANTS Multicenter randomized clinical trial performed at 8 adult ICUs in France from February 8, 2016, through April 29, 2017. A total of 198 ICU nurses were included and followed up for 1 year until April 30, 2018.

INTERVENTIONS The ICU nurses who had at least 6 months of ICU experience were randomized to the intervention group (n = 101) or to the control group (n = 97). The nurses randomized to the intervention group received a 5-day course involving a nursing theory recap and situational role-play using simulated scenarios (based on technical dexterity, clinical approach, decision making, aptitude to teamwork, and task prioritization), which were followed by debriefing sessions on attitude and discussion of practices.

MAIN OUTCOMES AND MEASURES The primary outcome was the prevalence of job strain assessed by combining a psychological demand score greater than 21 (score range, 9 [best] to 36 [worst]) with a decision latitude score less than 72 (score range, 24 [worst] to 96 [best]) using the Job Content Questionnaire and evaluated at 6 months. There were 7 secondary outcomes including absenteeism and turnover.

RESULTS Among 198 ICU nurses who were randomized (95 aged ≤30 years [48%] and 115 women [58%]), 182 (92%) completed the trial for the primary outcome. The trial was stopped for efficacy at the scheduled interim analysis after enrollment of 198 participants. The prevalence of job strain at 6 months was lower in the intervention group than in the control group (13% vs 67%, respectively; between-group difference, 54% [95% CI, 40%-64%]; $P < .001$). Absenteeism during the 6-month follow-up period was 1% in the intervention group compared with 8% in the control group (between-group difference, 7% [95% CI, 1%-15%]; $P = .03$). Four nurses (4%) from the intervention group left the ICU during the 6-month follow-up period compared with 12 nurses (12%) from the control group (between-group difference, 8% [95% CI, 0%-17%]; $P = .04$).

CONCLUSIONS AND RELEVANCE Among ICU nurses, an intervention that included education, role-play, and debriefing resulted in a lower prevalence of job strain at 6 months compared with nurses who did not undergo this program. Further research is needed to understand which components of the program may have contributed to this result and to evaluate whether this program is cost-effective.

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Working in an intensive care unit (ICU) is increasingly complex and physically, cognitively, and emotionally demanding. The ICU work environment requires nurses to deliver humane care in work environments that are becoming increasingly technical and are associated with growing responsibilities. Intensive care unit nurses are exposed to serious occupational stressors such as time pressure; reduced social support at work; excessive workloads; miscommunication; poor supervision; conflict with physicians, peers, patients, or families of patients; high job demands; and moral and spiritual distress related to end-of-life issues.[1-5] All these aspects require ICU nurses to maintain specialized knowledge and advanced skills to assess, monitor, and effectively respond to the needs of patients. Increased demands, together with persistent work-related stress, reduce individual job satisfaction and augment the risk of stress reactions, long-term absenteeism, and burnout.

Occupational stress and its consequences can be alleviated by modifying the work environment. Another approach is to improve the ability of caregivers to cope with stress. In this context, training can improve the nurse's ability to develop coping mechanisms against stress.

Simulation as a teaching and learning strategy is a widely used tool to train students for effective clinical practice. High-fidelity simulation is considered a viable method to enhance clinical skills, communication, clinical decision making, and critical thinking and to promote self-confidence and teamwork.[6,7] Furthermore, high-fidelity simulation has been associated with improved clinical outcomes and sustained improvement in nursing confidence and knowledge.[8,9]

The main objective of this trial was to assess whether a multifaceted education program that included simulation scenarios was effective in reducing job strain evaluated at 6 months. Secondary objectives included the evaluation of the effects of the intervention on other psychosocial factors at work (including burnout assessment) along with absenteeism and turnover.

Key Points

Question Can a multimodal program that includes education, role-play, and debriefing reduce job stress among intensive care unit (ICU) nurses?

Findings In this randomized clinical trial including 198 ICU nurses in France, the prevalence of job strain (assessed by a questionnaire that included psychological demand and decision latitude evaluation) was significantly reduced at 6 months among nurses in the 5-day intervention group (13%) compared with those in the control group (67%).

Meaning A multimodal program may be effective in reducing job stress among ICU nurses.

Methods

This open-label, multicenter randomized clinical trial including nurses was performed at 8 French adult medical, surgical, and mixed ICUs from February 8, 2016, through April 29, 2017, with follow-up until April 30, 2018. The trial protocol appears in Supplement 1 and the statistical analysis plan appears in Supplement 2.

The trial was approved by the institutional review board (Comité de Protection des Personnes Sud-Méditerrannée I), the advisory committee on the treatment of information in the field of health research (Comité Consultatif sur le Traitement de l'Information en Matière de Recherche dans le Domaine de la Santé; 15.498), and the French data protection authority (Commission Nationale de l'Informatique et des Libertés; DR-2015-556). Informed consent and demographic data were obtained from the participating nurses during individual meetings. Participation in the trial was voluntary and participants could withdraw at any time.

Inclusion and Exclusion Criteria

The inclusion criteria for the ICU nurses were: (1) actively working in an adult ICU, (2) held a registered nurse license, and (3) had at least 6 months' work experience in the current ICU. The sample consisted of day- and night-shift registered nurses who worked in 1 of the 8 ICUs participating in the trial (**Figure**). The exclusion criteria were: (1) current placement outside ICU, (2) on maternity or sick leave, (3) planning to leave ICU, or (4) already completed the simulation intervention prior to the beginning of the trial.

Randomization

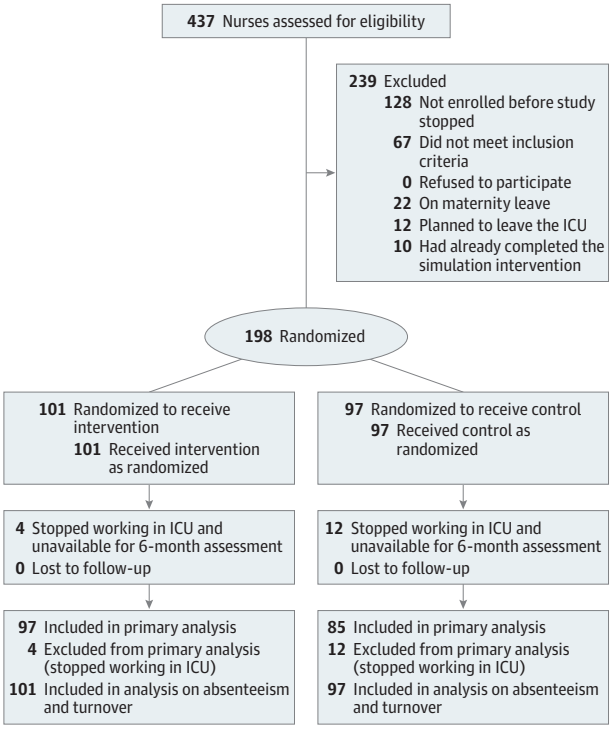
Individuals to be randomized were selected from ICU nurses willing to participate. Briefly, ICU nurses meeting the inclusion criteria were selected by lots drawn by the clinical research unit at the Assistance Publique-Hôpitaux de Marseille, which was not involved with the ICU. At each planned session, the chief nurse provided the clinical research unit with a list of nurses to participate in the program (each nurse chose an identification number). The clinical research unit selected 2, 4, 6, 8, 10, or 12 nurses to participate in the trial. Half of the selected nurses (1, 2, 3, 4, 5, or 6) were randomized to the intervention group and the other half were randomized to the control group.

Randomization was stratified by ICU site and job experience (6-24 months vs ≥24 months). Participants were randomly assigned using a computer-generated randomization list (allocation ratio of 1:1) and a permuted block design (block size range, 4-8). Participants from 1 to 3 ICUs were randomized to 1 of 2 equal-sized groups: (1) the 5-day intervention simulation training group or (2) the control group (nurses did not participate in simulation training but answered questionnaires). Prior to consent, it was explained that the nurses included in the control group would be able to participate in this simulation training program on a voluntary basis once the trial had been completed.

Intervention

The intervention was developed by a team at the simulation center of the Faculty of Medicine and Health Sciences, Aix-Marseille University, which comprises physicians and qualified nurses (each held a degree in simulation teaching). The 5-day course complied with recommendations from the French national health authority (Haute Autorité de Santé).[10] Each group of 6 ICU nurses in the intervention group attended the course

Figure. Flow of Intensive Care Unit (ICU) Nurses Through the Trial



for 3 consecutive days during the first week and for 2 consecutive days during the second week (additional information about the 5-day course appears in Supplement 3). The intervention took place during paid working hours and nurses were not reimbursed for participating in the trial. The 5-day intervention cost the employer approximately €2000 per nurse.

The intervention was intended to reduce job strain prevalence by improving the ability of ICU nurses to cope with stressful situations (eg, cardiac arrest, respiratory failure, and end-of-life issues) and cope with some stressors related to work organization (eg, task interruption, ambiguity of roles, and workload distribution) or working conditions (eg, lack of communication, and feelings of nonrecognition or lack of autonomy).

The general training objectives were to progress in the management of potentially iatrogenic situations or techniques and in clinical emergency management to (1) develop the skills expected in ICU nursing practice, (2) analyze the effect of stress and the emotions felt by nurses dealing with a difficult situation, (3) define strategies that allow him or her to ignore the emotions, (4) get to know his or her team, and (5) manage the quality of team relationships. The training course started with a nursing theory recap throughout day 1 and in the mornings on days 2 through 4. During the afternoons of days 2 through 4 and throughout day 5, nurses participated in simulation scenarios that focused on patients with deteriorating conditions, which were followed by debriefing sessions that discussed soft skills and practices. The simulated scenarios were based on nursing best practices.

Each scenario was written after having defined the learning objectives (technical dexterity, clinical approach, decision making, application of procedures, aptitude to working in a team, or task prioritization). Various topics included treatment of patients with cardiopulmonary arrest, chest pain, hemorrhagic shock, difficult intubation, end-of-life issues, and anaphylactic shock. An introductory briefing prepared the nurse for the simulation session, created a positive learning environment, encouraged emotional security, and guaranteed the respect of nondisclosure rules. Participants received a clinical sheet introducing the clinical situation being simulated. A simulated patient medical record, which included an ICU admission flowsheet, a medical prescription, and a nursing intervention sheet, was given to the participants. Each simulation sequence lasted 10 to 15 minutes and was recorded on video.

Once the targeted objectives were reached, the instructor stopped the scenario. Actors and observers met up for a debriefing session divided into 3 phases. First, there was a reaction or descriptive phase during which the nurses had the opportunity to give their impressions, describe and share their emotions, and discuss the stress caused by the simulation session. The second phase analyzed the session according to the learning objectives. The method used was a reflective process derived from the Situation, Background, Assessment, Recommendation communication tool.[11] This phase studied the reasons why actions were or were not done and analyzed the underlying clinical reasoning behind the decisions that were made. Video recordings were used as a debriefing support and enabled a more pertinent analysis of human behavior and a relational approach. The final summary phase concluded the debriefing. This phase was a means of reinforcing learning and going over the important messages identified during the second phase. The third phase also provided an opportunity to formulate future learning objectives.

Data Collection

Data collection was performed by 2 trained nurse researchers (R.E. and A.M.) to maintain consistency in the methods. Data collection took place at 3 time points: (1) at baseline before the intervention, (2) at 6 months after the intervention, and (3) at 12 months after intervention. At baseline, participants were asked to provide sociodemographic and occupational information regarding age, sex, level of education, nursing experience, experience in the hospital, experience in the current position, years of ICU experience, type of intensive care (surgical, medical, or mixed), and shift (day, night, or 12 hour). Participants also rated satisfaction at work using a scale from 1 (greatest dissatisfaction) to 10 (highest satisfaction); the scale used has not been validated.

Nurses were requested to fill out a battery of questionnaires including work-related job strain (Job Content Questionnaire [JCQ]) and psychosocial factors at work (Copenhagen Psychosocial Questionnaire [COPSOQ]). Nurses responded to the self-administered questionnaires within 2 hours of the beginning of a shift and were only given after at least 2 days off work. All questionnaires were anonymized and labeled with unique participant identifiers to maintain confidentiality.

Each participant was provided a unique identifier by a person not involved in survey administration or statistical analysis. The key containing participant names and identifiers was

kept in a secure location separate from the surveys and the data files. At 6 and 12 months after randomization, the nurses who were still working at their respective hospitals completed the questionnaires. Information regarding absenteeism and turnover were based on administrative data.

The JCQ

The Karasek model describes 2 particularly pathogenic situations: job strain, which combines high psychological demand and low decision latitude at work, and isostrain, which combines job strain and low social support. To determine job strain and isostrain, psychological demand, decision latitude, and social support were evaluated using the French version of the 26-item JCQ.[12,13]

The JCQ items were scored on a 4-point Likert-type scale with scores ranging from 1 (strongly disagree) to 4 (strongly agree). This questionnaire covers 3 dimensions: psychological demand (9 items evaluating the amount of work demanded, the rapidity required, the time available, and the level of concentration required; score range: 9 [the best] to 36 [the worst]), decision latitude (9 items evaluating decision authority, use of skills, and varied aspects of the tasks; score range: 24 [the worst] to 96 [the best]), and social support (8 items specifically evaluating the help and interest provided by colleagues and supervisors; score range: 8 [the worst] to 32 [the best]).[13]

From French data, the job strain threshold was set as a psychological demand score greater than 21 and a decision latitude score less than 72; the isostrain threshold was defined by the combination of job strain and a social support score less than 24.[14] In a large French survey including more than 24 000 workers from all professions, the prevalence of job strain was 23%.[13] The score ranges for psychological demand were from 19 to 25 and decision latitude ranged from 59 to 81,[13] suggesting that a difference of 1 or 2 points for psychological demand and of 2 to 4 points for decision latitude are relevant.

The COPSOQ

Originally developed in Denmark, the COPSOQ is a comprehensive tool for the assessment of psychosocial factors in the workplace.[15] The French version of the COPSOQ[16] was used in the present trial and it is composed of 46 items on 24 scales (including a burnout scale) representing 6 domains. The questions and scales are derived mostly from preexisting instruments and have the following response options: always, often, sometimes, rarely, or never/almost never to a great extent, to some extent, somewhat, a little, and very little.

Scores for each scale range from 0 to 100. For most of the factors, higher scores indicate better outcomes. For example, higher scores for burnout are better and the mean (SD) burnout score using this questionnaire was 52 (20) in a French sample.[16] However, lower scores indicate better outcomes for the demands domain (ie, a higher score indicates greater quantitative, work pace, or cognitive demands).

Primary Outcome

The primary outcome was job strain prevalence at 6 months (dichotomous variable defined as the combination of a psychological demand score >21 and a decision latitude score <72 measured by the JCQ).

Secondary Outcomes

The secondary outcomes were (1) the prevalence of isostrain at 6 months (dichotomous variable defined as the combination of job strain with a social support score <24 measured by the JCQ), (2) all dimensions evaluated by the JCQ (psychological demand, decision latitude, and social support) analyzed as continuous variables, (3) psychosocial factors in the workplace (including burnout) evaluated using the COPSOQ, (4) absenteeism defined as the proportion of ICU nurses missing at least 1 work day during the 6-month follow-up period after baseline, and (5) turnover.

For nurses who left the ICU during the trial, the period preceding their departure was considered for absenteeism (ie, if a nurse who left the ICU 4 months after baseline was never absent, he or she was considered as not being absent). Turnover was defined as the number of ICU nurses leaving their current positions during the 6-month follow-up period after baseline to work in a non-ICU ward or a non-nursing job. The prevalence of job strain and isostrain also were assessed at 12 months.

Sample Size Determination

Sample size was determined according to the prevalence of job strain. The prevalence is 23% for job strain among French workers in general,[13] whereas it is 60% for French nurses.[17] Because no randomized clinical trial had investigated the effect of an intervention on the reduction of job strain among health care workers, we arbitrarily chose a reduction in prevalence of 15% as clinically important.

A sample size of 188 participants per group was required to detect an absolute between-group difference of 15 percentage points (a relative reduction of 25%; 60% for the control group and 45% for the intervention group) and included an interim analysis after the inclusion of 50% of the participants with a power level of 80%. A *P* value threshold of .003 was used for the interim analysis and a *P* value threshold of .05 was used for the final analysis (version 11 of PASS [Power Analysis and Sample Size] software; J. L. Hintze). Furthermore, a dropout rate of 12 ICU nurses per group was anticipated, which led to a sample size of 200 participants per group.

Statistical Analysis

The analysis was performed on the intention-to-treat population (statistical analysis plan appears in Supplement 2). Data management and analysis were conducted blindly by the biostatistics team. A committee (Comité de Suivi de L'étude) composed of 2 of the investigators (R.E. and L.P.), a statistician (Anderson Loundou; Laboratoire de Santé Publique, Faculté de Médecine de Marseille), and the director of the Assistance Publique-Hôpitaux de Marseille Research Unit (Pascal Auquier) was responsible for the decision to stop or continue the trial after the interim analysis. Baseline parameters are presented per group. The trial was monitored using group sequential testing and the stopping rule was efficacy (less job strain among nurses in the intervention group) according to O'Brien-Fleming-type asymmetric boundaries.

The stopping boundary for the primary end point was to reach an absolute between-group difference of job strain prevalence of at least 20.6% and $P < .003$. The proportion of job strain at 6 months (primary outcome) was compared between the groups using the χ^2 test. Proportions of isostrain, absenteeism, and turnover at 6 months were compared using the χ^2 test or the Fisher exact test. Scores from the JCQ and COPSOQ were compared between the groups using the Mann-Whitney test. The between-group differences in psychological demand, decision latitude, and social support were compared using the Mann-Whitney test. Adjusted analyses were performed regarding potential confounding factors (differences observed for baseline characteristics) using logistic regression.

In addition, a series of post hoc analyses of the primary end point were conducted. A sensitivity analysis based on the definition of job strain used other cut points for psychological demand (score >20) and decision latitude (score <71) according to another large French study[13] using the χ^2 test. A post hoc analysis simultaneously treated psychological demand and decision latitude (2 dimensions used to define job strain) as continuous variables using a general linear model and the Wilks λ test. Because nurses leaving the ICU during the 6-month follow-up period were excluded from the primary analysis, a post hoc analysis using multiple imputations (5 data sets) was performed for the primary end point from 4 predictors (sex, age group, group assignment, ICU site) using logistic regression and the pooled results for the 5 data sets are presented. A potential ICU site effect was assessed by mixed-effects modeling using the GLIMMIX procedure (ICU site as a random effect, a logit-link function, and a binomial distribution function) and the result was presented as an odds ratio (occurrence of job strain for the control group vs the intervention group) and its 95% CI.

All statistical tests were 2-sided with a significance level of $P < .05$. There was no adjustment of the significance threshold for the secondary outcomes. Because of the potential for type I error, all of these analyses should be interpreted as exploratory. Statistical analyses were performed using SPSS version 20.0 (IBM) and SAS version 9.4 (SAS Institute Inc).

Results

Among 198 ICU nurses who were randomized (95 aged ≤30 years [48%] and 115 women [58%]), 182 (92%) completed the trial for the primary outcome. After the interim analysis, the Comité de Suivi de L'étude made the decision to stop the trial for efficacy. No nurse refused to participate in the trial. Of the 198 nurses randomized, 101 were randomized to the intervention group and 97 to the control group; all participants completed the baseline questionnaire. All 101 ICU nurses in the intervention group participated in the 5-day program. No participant withdrew his or her consent.

Regarding the psychosocial risk assessment per the prespecified trial protocol, only the nurses still working in the ICU were considered in the analysis (97 in the intervention group and 85 in the control group). However, all 198 ICU nurses were included in the evaluation of absenteeism and turnover. The baseline characteristics of the participants appear in **Table 1**. The only major between-group difference was in marital status (46% were single in the intervention group vs 62% in the control group).

Primary Outcome

A total of 182 nurses were still working in the same ICU at 6-month follow-up and completed the questionnaire; there were no missing data for the primary outcome. The prevalence of job strain at 6-month follow-up was lower in the intervention group (13%; 95% CI, 6%-20%) than in the control group (67%; 95% CI, 58%-76%) (between-group difference, 54% [95% CI, 40%-64%], $P < .001$; **Table 2**). Neither variable of marital status (odds ratio, 0.90 [95% CI, 0.43-1.87], $P = .78$; Hosmer-Lemeshow test $P = .96$) nor working the night shift (odds ratio, 0.53 [95% CI, 0.26-1.10], $P = .10$; Hosmer-Lemeshow test $P = .76$) was associated with job strain.

Secondary Outcomes

The prevalence of isostrain (job strain and low social support) was significantly decreased at 6-month follow-up in the intervention group compared with the control group (7% [95% CI, 2%-12%] vs 55% [95% CI, 45%-65%], respectively; between-group difference, 48% [95% CI, 35%-59%], $P < .001$). All these between-group differences regarding job strain and isostrain remained significant at 12-month follow-up in the 93 questionnaires analyzed (Table 2). Absenteeism during the 6-month follow-up was 1% in the intervention group compared with 8% in the control group (between-group difference, 7% [95% CI, 1%-15%], $P = .03$).

In addition, 4 nurses (4%) in the intervention group left the ICU during the 6-month follow-up compared with 12 nurses (12%) in the control group (between-group difference, 8% [95% CI, 0%-17%], $P = .04$). No nurse moved from one ICU to another during the entire trial period.

A detailed description of the 3 dimensions of the Karasek model (psychological demand, decision latitude, and social support) from baseline to 6-month follow-up appears in **Table 3** (raw values) and in the eTable (prevalence) in Supplement 4. The magnitude of the decrease in the score for psychological demand was greater at 6 months in the intervention group than in the control group (mean difference, −5.5 [95% CI, −6.7 to −4.3] vs −0.7 [95% CI, −1.8 to 0.4], respectively; between-group mean difference, −4.8 [95% CI, −6.4 to −3.2], $P < .001$; Table 3). Similarly, the magnitude of the score increase was greater at 6 months in the intervention group than in the control group for both decision latitude (mean difference, 18.4 [95% CI, 14.7 to 22.2] vs −5.1 [95% CI, −9.4 to −0.7], respectively; between-group mean difference, 23.5 [95% CI, 17.8 to 29.2]) and for social support (mean difference, 2.0 [95% CI, 0.5 to 3.5] vs −2.6 [95% CI, −4.3 to −1.0]; between-group mean difference, 4.6 [95% CI, 2.4 to 6.8]; $P < .001$ for both comparisons).

Among nurses in the intervention group compared with the control group, the prevalence decreased at 6 months for high psychological demand (27% vs 72%, respectively; between-group difference, −45% [95% CI, −56% to −31%], $P < .001$), for low decision latitude (15% vs 68%; between-group difference, −53% [95% CI, −63% to −39%], $P < .001$),

Table 1. Baseline Characteristics of the Participants

	No. (%) of Participants	
	Intervention Group (n = 101)	Control Group (n = 97)
Age group, y		
≤30	49 (49)	46 (47)
31-40	45 (45)	43 (44)
≥41	7 (7)	8 (8)
Women	61 (60)	54 (56)
Men	40 (40)	43 (44)
Single, not married	46 (46)	60 (62)
No. of children		
0	66 (65)	69 (71)
1	21 (21)	17 (18)
2	9 (9)	8 (8)
>2	5 (5)	3 (3)
Length of commute, min		
<15	35 (35)	31 (32)
15-30	50 (50)	56 (58)
>30	16 (16)	10 (10)
Work status		
Full time	101 (100)	97 (100)
Day shift	69 (68)	53 (55)
12-h shift	101 (100)	97 (100)
ICU rotation as part of nursing school	81 (80)	78 (80)
Time working as a nurse with RN license		
6 mo-1 y	14 (14)	15 (16)
1-2 y	26 (26)	28 (29)
2-5 y	32 (32)	27 (28)
6-10 y	20 (20)	18 (19)
>10 y	9 (9)	9 (9)
Time working as a nurse or nurse's assistant in ICU		
6 mo-1 y	15 (15)	17 (18)
1-2 y	28 (28)	30 (31)
2-5 y	35 (35)	28 (29)
6-10 y	18 (18)	16 (17)
>10 y	5 (5)	6 (6)
Time working in the current hospital as a nurse or nurse's assistant		
6 mo-1 y	13 (13)	16 (17)
1-2 y	28 (28)	28 (29)
2-5 y	30 (30)	26 (27)
6-10 y	21 (21)	20 (21)
>10 y	9 (9)	7 (7)
Never or rarely discussed job with friends or family	28 (28)	25 (26)
Never or rarely had telephone calls or emails for professional issues when not working	73 (72)	76 (78)
Always or often informed on time regarding modifications to job schedule	62 (61)	60 (62)
Level of satisfaction at work, median (interquartile range)[a]	7 (6-8)	7 (6-8)

Abbreviations: ICU, intensive care unit; RN, registered nurse.

[a] Nurses selected an integer from 1 (greatest dissatisfaction) to 10 (greatest satisfaction).

and for low social support (51% vs 76%; between-group difference, −26% [95% CI, −38% to −12%], $P < .001$; eTable in Supplement 4).

Regarding the various dimensions evaluated by the COPSOQ, ICU nurses in the intervention group had better outcomes at 6 months than nurses in the control group (**Table 4**). Job satisfaction was better in the intervention group compared with the control group (mean [SD] score, 82.5 [25.5] vs 54.9 [30.3], respectively; between-group mean difference, 27.6 [95% CI, 19.3-35.9], $P < .001$; Table 4). In addition, symptoms of burnout were less present in the intervention group than in the control group (mean [SD] score, 87.4 [23.7] vs 51.2 [29.3],

Table 2. Main Outcome Measures

	No. of Observations/Total No. (%)		Between-Group Difference, % (95% CI)	P Value[a]
	Intervention Group	Control Group		
Primary Outcome				
Job strain at 6 mo[b]	13/97 (13)	57/85 (67)	54 (40-64)	<.001
Secondary Outcomes				
Isostrain at 6 mo[c]	7/97 (7)	47/85 (55)	48 (35-59)	<.001
High psychological demand at 6 mo	26/97 (27)	61/85 (72)	45 (31-56)	<.001
Low social support at 6 mo	49/97 (51)	65/85 (76)	26 (12-38)	<.001
Low decision latitude at 6 mo	15/97 (15)	58/85 (68)	53 (39-63)	<.001
Absenteeism during 6-mo follow-up	1/101 (1)	8/97 (8)	7 (1-15)	.03
Left ICU during 6-mo follow-up[d]	4/101 (4)	12/97 (12)	8 (0-17)	.04
Job strain at 12 mo[b]	21/57 (37)	26/36 (72)	35 (15-52)	<.001
Isostrain at 12 mo[c]	8/57 (14)	24/36 (67)	53 (33-67)	<.001

Abbreviation: ICU, intensive care unit.

[a] Calculated using the χ^2 test for most comparisons. The Fisher exact test was used for absenteeism.

[b] Defined by the association of a psychological demand score greater than 21 and a decision latitude score less than 72 (measured by the Job Content Questionnaire).

[c] Defined by the association of a job strain score (a psychological demand score >21 and a decision latitude score <72 measured by the Job Content Questionnaire) and a social support score less than 24 (measured by the Job Content Questionnaire).

[d] None of the 16 nurses moved to a different ICU setting.

Table 3. Progression From Baseline to 6-Month Follow-up for the 3 Dimensions of the Karasek Model

	Intervention Group			Control Group			Intervention vs Control	
	Mean (SD) Score			Mean (SD) Score				
	Baseline (n = 101)	6-mo Follow-up (n = 97)	Mean Difference (95% CI)	Baseline (n = 97)	6-mo Follow-up (n = 85)	Mean Difference (95% CI)	Between-Group Mean Difference (95% CI)	P Value[a]
Psychological demand[b]	26.4 (5.4)	20.9 (4.5)	−5.5 (−6.7 to −4.3)	25.3 (5.5)	24.9 (5.5)	−0.7 (−1.8 to 0.4)	−4.8 (−6.4 to −3.2)	<.001
Decision latitude[c]	63.3 (15.8)	81.7 (14.6)	18.4 (14.7 to 22.2)	64.2 (16.3)	59.3 (21.1)	−5.1 (−9.4 to −0.7)	23.5 (17.8 to 29.2)	<.001
Social support[d]	20.8 (6.4)	22.6 (6.3)	2.0 (0.5 to 3.5)	20.4 (5.8)	18.2 (7.5)	−2.6 (−4.3 to −1.0)	4.6 (2.4 to 6.8)	<.001

[a] Calculated using the Mann-Whitney test.

[b] Composite score for 9 items evaluating the amount of work demanded, the rapidity required, the time available, and the level of concentration required. Higher scores indicate greater demand; score range: 9 (the best) to 36 (the worst).

[c] Composite score for 9 items evaluating decision authority, use of skills, and varied aspects of the tasks. Higher scores indicate greater latitude; score range: 24 (the worst) to 96 (the best).

[d] Composite score for 8 items specifically evaluating the help and interest provided by colleagues and supervisors. Higher scores indicate greater support; score range: 8 (the worst) to 32 (the best).

respectively; between-group mean difference, 36.2 [95% CI, 28.3-44.1], $P = .001$; Table 4).

Post hoc Analyses

The prevalence of job strain was lower in the intervention group than in the control group (14% [95% CI, 7%-21%] vs 68% [95% CI, 58%-78%], respectively, $P < .001$) using the cut point of 20 for the psychological demand score and 71 for the decision latitude score. When psychological demand and decision latitude were treated as continuous variables, the general linear model confirmed that the intervention was associated with significantly lower psychological demand and higher decision latitude compared with the control (Wilks λ test $P < .001$ and $P < .001$, respectively).

Using multiple imputation for the primary outcome, the pooled results revealed a job strain prevalence of 15% in the intervention group compared with 65% in the control group ($P < .001$). No ICU site effect was identified using mixed-effects modeling. The odds ratio was 9.9 (95% CI, 4.2-23.5, $P < .001$) using the random-effects model compared with 13.1 (95% CI, 6.3-27.5, $P < .001$) without using the model.

Discussion

An intervention for ICU nurses that included education, role-play, and debriefing resulted in a lower prevalence of job strain at 6 months compared with nurses who did not follow this program (control group). Although some stress may have positive effects on work, repeated or excessive stress may result in anxiety, distress, burnout, depression, or even posttraumatic stress disorder. Nurses working in ICUs are at particular risk for the negative effects of stress.[18] Nurses practicing in ICUs and emergency departments are at particularly high risk of job strain.[19-21]

Occupational stress and its harmful consequences may be reduced by modifying the work environment or improving the individual's ability to cope with stress. Training may improve the ability to adapt by encouraging determination

Table 4. Psychological Factors at Work Evaluated at 6 Months Using the Copenhagen Psychosocial Questionnaire

	Mean (SD) Score[a]		Between-Group Mean Difference (95% CI)	*P* Value[b]
	Intervention Group (n = 97)	Control Group (n = 85)		
Demands domain[c]				
Quantitative demands	45.6 (15.8)	61.9 (24.4)	−16.3 (−22.4 to −10.2)	<.001
Work pace	62.1 (12.3)	76.5 (18.1)	−14.4 (−19.0 to −9.8)	<.001
Cognitive demands	72.7 (15.5)	81.0 (17.3)	−8.3 (−13.1 to −3.6)	<.001
Work organization and job content				
Influence at work	79.9 (22.6)	36.6 (30.8)	43.3 (35.3 to 51.3)	<.001
Possibilities for development	80.9 (22.1)	49.7 (31.5)	31.2 (23.2 to 39.3)	<.001
Interpersonal relationship and leadership domain				
Predictability	77.4 (21.5)	56.0 (19.3)	21.4 (15.5 to 27.4)	<.001
Rewards or recognition	71.4 (29.0)	51.3 (30.6)	20.1 (11.3 to 28.8)	<.001
Justice and respect	47.8 (21.9)	43.5 (23.9)	4.3 (2.4 to 11.0)	.16
Role clarity	83.8 (20.0)	63.5 (27.4)	20.2 (13.1 to 27.3)	<.001
Role conflicts	67.5 (19.2)	55.1 (21.2)	12.5 (6.5 to 18.4)	<.001
Quality of leadership	36.1 (30.1)	49.0 (34.0)	−12.9 (−22.3 to −3.5)	.004
Social support from supervisor	48.3 (30.8)	45.6 (31.5)	2.7 (−6.9 to 11.9)	.65
Trust regarding management	69.2 (30.2)	56.0 (34.0)	13.2 (3.8 to 22.6)	.007
Relationship with colleagues				
Trust between colleagues	79.5 (24.6)	49.6 (32.7)	30.0 (21.4 to 38.5)	<.001
Social support from colleagues	64.7 (28.2)	42.1 (37.6)	22.6 (12.8 to 32.5)	<.001
Influence and development domain				
Meaning of work	87.2 (16.0)	66.6 (25.5)	20.6 (14.3 to 27.0)	<.001
Workplace commitment	52.2 (16.4)	51.2 (16.9)	1.0 (−3.9 to 5.9)	.83
Job satisfaction	82.5 (25.5)	54.9 (30.3)	27.6 (19.3 to 35.9)	<.001
Health and well-being domain				
Self-rated health	88.8 (16.6)	80.2 (23.2)	8.6 (2.6 to 14.7)	.01
Stress	87.0 (24.7)	53.4 (28.4)	33.6 (25.8 to 41.4)	<.001
Burnout[d]	87.4 (23.7)	51.2 (29.3)	36.2 (28.3 to 44.1)	.001
Emotional demands	59.7 (16.1)	47.6 (24.7)	12.0 (5.8 to 18.2)	.002
Work or family conflict	89.4 (21.1)	71.6 (23.7)	17.8 (11.2 to 24.4)	.001
Job insecurity	93.4 (17.8)	96.3 (11.5)	−3.0 (−7.2 to 1.4)	.55

[a] Scores range from 0 to 100; higher scores indicate better outcomes unless otherwise indicated.

[b] Calculated using the Mann-Whitney test.

[c] Lower scores indicate better outcomes because higher scores indicate greater demands.

[d] In a study of French employees of a large firm in the Parisian area,[16] the mean (SD) burnout score was 52 (20).

and shaping the style of coping with stressful situations.[22] These mechanisms may explain the beneficial effect on the reduction of job strain found in the present trial. Simulation scenarios of ICU care provide updates of technical and nontechnical knowledge and skills for nurses.[23] These simulation scenarios also may improve the ability to cope with stressful situations. Simulation may affect stressors related to work organization (task interruption, ambiguity of roles, workload distribution) or to working conditions such as lack of communication or lack of autonomy.[24]

The intervention tested in the present trial may have helped decrease high psychological job demands such as having to work under time pressure or having to cope with complex, mentally demanding tasks. It may have improved the degree of control (decision latitude) ICU nurses have over their tasks and behaviors in performing their daily work.

Increased demands and persistent work-related stress reduce individual job satisfaction and augment the risk of stress reactions and burnout.[25-28] This stress process ultimately results in poor individual health, diminished professional success, long-term absenteeism, and increased rates of turnover, thereby affecting hospital finances due to ICU nurses leaving their jobs.[29] The prior findings[25-28] are concordant with the results presented herein. The participants included in the control group had worse self-rated health than the ICU nurses included in the intervention group. In addition, more ICU nurses left their jobs in the control group than in the intervention group.

It has been reported that approximately 25% of French nurses have job strain,[13] and social support plays a moderating role on their well-being. However, that study[13] did not differentiate nurses according to the type of service in which they worked. To our knowledge, only 1 study has assessed work-related psychological issues among 89 ICU nurses from the same center,[21] and job strain was observed in 70%. This percentage is roughly the same proportion observed at baseline in the present trial.

Limitations

This trial has several limitations. First, this trial included only French ICU nurses. These results need to be reassessed in different places around the world.

Second, an adequate follow-up timeframe after the intervention needs to be defined. It is highly plausible that a single 5-day simulation program is unable to reduce the number of nurses leaving ICUs during a period exceeding 1 year. The need to readminister these programs should be assessed.

Third, other means of stress reduction can be implemented such as providing employee wellness programs, employee health screenings, adequate staffing, interdisciplinary debriefing following difficult cases, and support programs with role models, preceptors, or mentors.[30]

Fourth, the chosen randomization scheme at the nurse level rather than at the ICU level may have contaminated the control group because the nurses receiving the 5-day intervention training course could have passively or actively transmitted their new knowledge to the nurses in the control group who did not receive the training. This would have biased the results toward null; therefore, it is not relevant given the trial results.

Fifth, there may have been an unintended negative effect on the control group of nurses who would have witnessed the intervention nurses receiving the 5-day training and teambuilding course. This may have resulted in a feeling of hierarchy or jealousy of others receiving special treatment and may have contributed to job-related distress. However, to prevent and limit these feelings, ICU nurses randomized to the control group were informed prior to giving consent that they would be able to enroll in the program on a voluntary basis once the trial had been completed.

Sixth, the intervention has to be standardized to be easily replicated in other ICUs located in other countries.

Seventh, selection of the proper control intervention is one of the more difficult aspects of designing such a clinical trial. When no active control group is used, the success of the intervention may be related to increased attention or other nonintervention-related effects. Considerable emotional strength can be fostered from close relationships with friends, coworkers, and organizations. It is possible that delivering additional support and attention may be sufficient to reduce job strain.

It is unlikely that this 5-day intervention delivered by people unfamiliar with coaching methods for caregivers would be able to provoke such a decrease in the prevalence of job strain evaluated 6 months later if this was only related to relationships and not related to technical aspects in the ICU. However, it could be an important aspect of this multimodal program's beneficial effect and needs further investigation, particularly regarding the potential economic consequences (balancing the cost of the program with turnover and absenteeism).

Eighth, due to the lack of other interventional trials aiming to reduce job strain among nurses, the present sample size was based on an assumption that a reduction of 15% in job strain prevalence would be clinically relevant. The reduction of both absenteeism and turnover reported in the present trial validates this hypothesis.

Conclusions

Among ICU nurses, an intervention that included education, role-play, and debriefing resulted in a lower prevalence of job strain at 6 months compared with nurses who did not undergo this program. Further research is needed to understand which components of the program may have contributed to this result and to evaluate whether this program is cost-effective.

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