Effectiveness and cost-effectiveness of Crew Resource Management training to improve patient safety at intensive care units.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27873

Source
Nationaal Trial Register

Brief title
N/A

Health condition

patient safety, adverse events, intensive care

Sponsors and support

Primary sponsor: QST safe skies provides the training at a scientific tarif
Source(s) of monetary or material Support: ZONMW doelmatigheid

Intervention

Outcome measures

Primary outcome

Patient safety:

1. Adverse event rate;

2. Safety culture.

Secondary outcome

1. Knowledge, attitude and behavior with regard to TRM principles;

2. Activities to improve patient safety.

Study description

Background summary

Objective:
To assess the (cost)effectiveness of CRM training to improve patient safety at intensive care units (ICU).

Design:
In a paired cluster-randomized trial with one pre-test and one post-test measurement 3 ICUs with CRM training will be compared with 3 ICUs without training.

Intervention:
The intervention group will take part in CRM training, in which all icu team members are educated about the limitations of human performance, nontechnical skills, patient safety culture and leadership in order to improve detection and management of errors. Furthermore, participants are trained to assess personal and peer behaviour. The training consists of an e-learning module (1 hour), a 2-day CRM training with two half-day comeback sessions are given by two trainers (behavioural scientist + clinician) to all ICU workers. In addition, a change-team will be formed to support and coordinate implementation of CRM.

Outcomes:
The primary outcome is the number of adverse events per patient day assessed by means direct structured observations and ICU-specific adverse outcomes assessed by routine administrative data. Secondary outcomes include patient safety culture, percentage of errors managed effectively and attitudes towards CRM, assessed by means of questionnaires and direct structured observations after 0 and 10 months.
Sample size and data-analysis: Sample size calculation is based on incidence rates transformed to z values of the incidences of adverse

events per patient day. As the paired design compensates for the inefficiencies of the clustering, no correction for clustering was applied. If we assume that the incidence of adverse events at ICU departments is 10%, the control group will reduce adverse events to 9% and the intervention group to 5%, alpha is 0.05, beta is 0.80, than we need to observe 1100 patient days per group per measurement moment to detect a difference. Differences in change in incidence of adverse events during follow-up between both groups will be assessed using incidence rates transformed to z values of the incidence percentages. Changes in patient safety culture, attitude and teamwork behaviour will be described and tested using t-test and Chi-square tests.

Economic evaluation:
A cost-effectiveness analysis will be performed to assess the incremental costs per prevented adverse event. In addition a cost-benefit analysis will be performed to compare incremental costs of training with incremental costs of ICU stay.

Time schedule:
The study will take 3 years, and measurements will be performed at 0 and 12 months.

Study objective

By improving non-clinical skills, such as communication, task coordination, collaboration and leadership of ICU staff, the ICU teams will improve their ability to detect and trap errors and threats and to diminish their harmfull consequences to patients.

Study design

Before and 12 months after the training all outcomes will be assessed.

Intervention

1. 3 intervention icu's and 3 matched control icu's;

2. All staff members and all participants.

Contacts

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Eligibility criteria

Inclusion criteria

1. All staff members of the participating ICU;

2. All patients admitted to ICU.

Exclusion criteria

None.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2009
Enrollment:	6
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1864
NTR-old	NTR1976
Other	ZonMW : 80-82310-98-09095
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A