Prevention of Health Care Workers* Health Problems after Work Related Critical Incidents: A Randomized Controlled Trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33841

Source
ToetsingOnline

Brief title
skills@work

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
acute stress, traumatic stress / long-term exhaustion, vital exhaustion

Health condition

burnout

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Fondsen worden aangevraagd.,Fondsen worden aangevraagd.

Intervention

Keyword: Health Care Workers, Post-Traumatic Stress Disorder, Prevention & Control, Professional Burnout

Outcome measures

Primary outcome

Main study parameters: The main study parameters are the incidence of symptoms

of Post Traumatic Stress Disorder, Burnout and Absenteeism four weeks post

incident.

Secondary outcome

Secondary endpoint is the score on the Trauma Screening Questionnaire two weeks

post incident.

Study description

Background summary

Only recently researchers have started to examine the impact of acute stressors (critical incidents) in the workplace, next to chronic job stressors. High rates of (symptoms of) Post Traumatic Stress Disorder (PTSD) have been reported among health care workers in acute settings, which negatively impact their well being and their attitude towards the job. Chronic job demands (e.g. demanding contacts with patients, time constraints, poor communication) are positively related to burnout (exhaustion and disengegement). With regard to the expected shortage of health care workers in the Netherlands in the near the future, impaired well being and disengagement may lead to serious problems; not only for the individual health care worker, but also for the organization, and for

society. Preventive programs should protect and support health care professionals after work-related critical incidents (Arbo-wet, 1994). Until now however, no consensus exists with regard to the content of preventive intervention after critical incidents.
Job resources (e.g. autonomy, social support, relationship with supervisor) are considered health-protecting factors, that buffer the impact of high job demands on burnout. Lack of resources leads to disengagement and indirectly to short-term absenteeism. The impact of critical incidents on outcomes, like posttraumatic responses, exhaustion, and absenteeism may also be buffered by job resources (i.e. psycho education, social support, autonomy, support from co-workers, and supervisor support). Besides, job resources may exert their effect (partly) via personal resources (e.g. self-efficacy, self esteem, resilience, optimism; see work model, page 21).
Neuro-endocrine response: In this study, the neuro-endocrine response to stress (i.e. cortisol, and dehydroepiandrosterone/DHEA) is included as the more objective measure of stress (next to self report questionnaires). Although, in PTSD, hyper-regulated stress systems (low cortisol baseline level in combination with over reactiveness to stress), as well as the opposite have been found, DHEA to cortisol ratio may index the degree to which an individual is buffered against the negative effects of stress.
Also in burnout-patients mixed results with respect to cortisol levels have been found. However, when hormone levels and exhaustion symptoms were simultaneously assessed (in a diary study), more severe burnout symptoms were consistently associated with lower levels of cortisol, smaller Cortisol Awakening Rise, and smaller cortisol to DHEA ratios.

Study objective

Primary objective of the study is to test the effectiveness of two interventions (by comparison with a control intervention and by mutual comparison) in preventing the negative effects of critical incidents and chronic job demands on the outcomes: posttraumatic responses, exhaustion, (dis)engagement, absenteeism, and satisfaction with help after critical incidents.

Secondary objectives are:
a) to examine inter-correlations of critical incidents, chronic job demands, job resources and personal resources, in inducing ASD/PTSD symptoms, general health problems, depression, anxiety, substance abuse (tobacco, alcohol, medication), exhaustion, disengagement, and absenteeism; across time, for the three conditions (see model 1, p. 21).
b) to determine stress hormone levels in saliva, to explore associations between DHEA to cortisol ratio in saliva and ASD/PTSD, burnout symptoms, cognitive appraisal and coping (by simultaneous registration in a diary, thus capturing states instead of constructs).

Study design

The study is longitudinal, randomized, *placebo* controlled (for flow chart, see p. 25-26).

Intervention

The Controlgroup receives a *placebo* intervention (watchful waiting). Interventiongroup-1 receives watchful waiting + psycho-education. Interventiongroup-2 receives watchful waiting + psycho-education + incident focussed social support from trained colleagues (see flow chart p 26, and teratment of subjects section, page 26-37).

Study burden and risks

The expected burden mainly originates from completing the questionnaires (appendices 1, 4, 5, 6), keeping a diary, and saliva sampling (appendix 9a - 9f). The risks associated with participation consist of extra workload for the colleague-supporters. There may be a risk of initially having more instead of fewer complaints, induced by higher awareness (as a result of psycho-education and questionnaire-items). Although in the intervention groups, this is not what we expect, as we explicitly label possible responses as normal reactions to abnormal situations that will probably disappear in a few days to weeks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Meeting with a work-related critical incident (critical incidents will be further defined after a first inventarisation in the in D3 mentioned wards)
Working in the present ward for at least 6 months at T0

Exclusion criteria

Current serious psychiatric disorder, that needs treatment before any other intervention could be applied
Currently under treatment for any psychiatric problem

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	25-05-2009
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL23132.078.08