

Design of a randomized controlled trial on the effects of COounseling of mental health problems by Occupational Physicians on Return to Work: the CO-OP-study.

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The objective of this study is to assess the effects of treatment by the occupational physician of employees with mental health problems according to the guideline, compared with usual care.

Ethical review	Approved WMO
Status	Pending
Health condition type	Adjustment disorders (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON31078

Source

ToetsingOnline

Brief title

CO-OP-study

Condition

- Adjustment disorders (incl subtypes)

Synonym

common mental health problems

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van Binnenlandse Zaken;Commit Arbo;VUmc

Intervention

Keyword: common mental health problems, guideline, occupational health, return to work

Outcome measures

Primary outcome

Return to work (RTW) was chosen as the primary outcome in this study with a follow-up time of one year after inclusion. Treatment satisfaction by employee, employer and the treating occupational physician is another primary outcome

Secondary outcome

Cost-effectiveness of the intervention is a secondary outcome and was evaluated from the employers and the health care insurance company*s perspective (expenditures for the employer and insurance company, respectively), as they are responsible for covering the costs of sick leave and treatment.

Study description

Background summary

Mental health problems often lead to prolonged sick leave. In the Netherlands, mental health problems are responsible for approximately one third of all employees disabled for over a year. Many share the view that better treatment and early intervention could prevent long lasting disability for work. Early 2000, the Dutch Association of Occupational Physicians (NVAB) has published an authorized guideline concerning the management of employees with mental health problems by occupational physicians.

Study objective

The objective of this study is to assess the effects of treatment by the occupational physician of employees with mental health problems according to the guideline, compared with usual care.

Study design

In a randomized controlled trial (RCT), subjects in the intervention group were treated according to the guideline. The control group received usual care, with minimal involvement of the occupational physician and frequent referral to a psychologist.

Intervention

The intervention consisted of treatment by OPs according to the guideline of employees on sick leave due to mental health problems. The guideline promotes a more active role of the OP as case and care manager facilitating return to work of the employee. The guideline is based on an activating approach, time contingent process evaluation and cognitive behavioral principles. The latter mainly concern stress inoculation training and graded activity and aim to enhance the problem-solving capacity of patients in relation to their work environment.

The guideline focuses on four aspects of the management of mental health problems. First, an early and activating guidance by the OP is promoted, in which return to work is part of the recovery process, even if the mental health problems are not related to work. Second, a simplified classification of mental health problems is introduced, with only four categories: 1) adjustment disorder (distress, nervous breakdown, burnout), 2) depression, 3) anxiety, and 4) other psychiatric disorders. Third, the OP acts as case manager, who is stimulated to be a care manager by counselling employees with adjustment disorders and work-related problems. Fourth, the OP performs a time contingent process evaluation and intervenes when recovery stagnates.

OPs participating in the study received training in the guideline before the study started.

Study burden and risks

not applicable

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

As the guideline focuses on all kinds of mental health problems, we aimed to include employees with a broad range of mental health problems consulting their OP. Employees were included if they met the following inclusion criteria:

- Mental health problems according to the diagnosis of the OP
- Sick leave at the moment of inclusion
- Sick leave period did not start before 2002.

Exclusion criteria

Exclusion criteria were the same as stated in the OP-guideline:

- Mental health symptoms that were caused by somatic illness
- Disagreement between OP and employee about the diagnosis
- Lack of confidence in the relation between OP and employee

The application of the exclusion criteria was dependent on the OPs expert judgement. To prevent selection bias, employees were not included of whom the period of sick leave started before 2002.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2002
Enrollment:	268
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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

ISRCTN

CCMO

ID

ISRCTN34887348

NL18371.029.07