Tools for Two: The SHARP-at work study. Effectiveness of an intervention Stimulating Healthy participation And Relapse Prevention. A cluster randomised controlled trial.

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First, to determine the effectiveness of the intervention in preventing recurrent sickness absence in employees who have returned to work after a period of sickness absence because of a common mental disorder. Second, to determine the effectiveness...

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

Summary

ID

NL-OMON32947

Source
ToetsingOnline

Brief title
Tools for Two: The SHARP-at work study.

Condition

- Adjustment disorders (incl subtypes)

Synonym
common mental disorders; mental overload

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stichting instituut GAK

Intervention

Keyword: cluster randomised controlled trial, common mental disorders, participation, relapse prevention

Outcome measures

Primary outcome

A change in days of recurrent sickness absence with a power of 80% at p<.05.

Secondary outcome

A change in mental health, work functioning and coping.

Cost-effectiveness of the intervention and the evaluation of the intervention

process.

Study description

Background summary

Common mental disorders, such as depression, anxiety disorder, and adjustment disorder, have emerged as a major public and occupational health problem in many countries. These disorders can have severe consequences such as absenteeism and work disability. Different interventions have been developed to improve the return to work of these employees, but still a large proportion of employees experiences health and work problems after their return to work. For this reason, an intervention will be developed to prevent recurrent sickness absence in employees who have returned to work after a period of sickness absence because of common mental disorders. This protocol describes the intervention and the effectiveness evaluation.

Study objective

First, to determine the effectiveness of the intervention in preventing recurrent sickness absence in employees who have returned to work after a period of sickness absence because of a common mental disorder. Second, to

determine the effectiveness of the intervention in improving mental health and work functioning, and facilitating an adequate coping style. Next to the effect evaluation, the cost-effectiveness and the process of the intervention will be evaluated.

Study design

A cluster randomised controlled trial with randomisation at the level of the occupational physician. Occupational physicians will be randomly assigned to the intervention condition or the control condition. Occupational physicians in the intervention condition will receive a training in the intervention. Occupational physicians in the control condition will deliver care as usual.

Intervention

Employees in the intervention condition will be supported during their first weeks after return to work by their occupational physician. This intervention is an extension of the guideline of the Dutch Association for Occupational Physicians on treating sickness absence because of mental health problems. Employees in the control group will receive care as usual.

Study burden and risks

The burden of the intervention is acceptable. It comprises four to five consultations with the occupational physician and (if approved by the employee) at least one of these consultations will be attended by the supervisor. Not all these consultations are additional because in the control condition the occupational physicians will also have consultations (according to the guideline). Questionnaires on work and health will be collected at baseline, 3, 6, and 12 months follow-up. Moreover, the employee will be asked to complete a diary over a period of four weeks at 2, 5 and 11 months follow-up.
So far no adverse side effects have been reported of interventions related to the present intervention. No major risks are anticipated for the intervention.

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

Employees;* Adult between 18 and 63 years old
* Employed in a paid job
* A period of sickness absence of at least two weeks
* A planned return to work within two weeks
* Diagnosed with a common mental disorder by the occupational physician at the start of the sickness absence period

Exclusion criteria

Employees;* Period of sickness absence because of a common mental disorder in the year prior to the present sickness absence spell
* Period of sickness absence longer then 12 months
* Severe mental disorders like personality disorders, psychotic disorders, bipolar disorder, and PTSD
* Alcohol and/or drug abuse
* Predominant influence of somatic complaints or disorders on work disability
* Pregnancy
* Upcoming retirement, resignation, discharge, or sabbatical
* Inability to understand, speak, read, and write the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2010
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL27916.042.09