Doelmatigheid van digitale werkhervattingsmodule bij depressieve werknemers.

No registrations found.

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

Summary

ID

NL-OMON27664

Source
NTR

Brief title
ECO

Health condition

workers on sick leave due to major depressive disorder

Sponsors and support

Primary sponsor: Trimbos-instituut
Zorg, Behandeling en Reintegratie
Programma Diagnostiek en Behandeling
Da Costakade 45
Postbus 725
Source(s) of monetary or material Support: Zonmw Doelmatigheid

Intervention

Outcome measures

Primary outcome

Time to first return to work (RTW)

Secondary outcome

Secondary outcome measures are severity of depressive, anxiety and somatization symptoms in terms of respons and remission, as measured with the Patient Health Questionnaire subscale for depression (PHQ9) and somatization (PHQ15) and the Generalized Anxiety Disorder Questionnaire (GAD7). Tertiary outcome is the cost-effectiveness.

Study description

Background summary

Background

The burden of CMD on the level of sickness absence is huge, for society as well as for individual workers. Given the implications for the workers quality of life and the huge costs incurred by sickness absence, return to work (RTW) is an important issue. In the Netherlands, the occupational physician (OP) plays a central role in the guidance of sick listed workers in RTW. Evidence based guidelines for OPs are available, but the availability of guidelines alone is not sufficient. An intervention is needed which supports the OP in the guidance of sick listed workers with CMD. The ECO-intervention comprises a decision aid supporting the OP and an E-health module for the depressed,
sick listed worker.

Methods-design

ECO is a two-armed cluster-randomized trial in which the ECO-intervention for CMD will be compared to usual care (CAU). Randomization will occur at the level of OPs. Workers on sickness absence between 4 and 26 weeks will be included in the study. OPs allocated to the intervention group will receive training in following up on the recommendations derived from the decision aid. Workers whose OP is allocated to the intervention group will receive the ECO-intervention: they will receive guidance from their OP following the decision aid system, and they will work through the E-health module. OPs allocated to CAU will give sickness guidance as usual. Follow-up measurements will
take place at 3, 6, 9 and 12 months after baseline. Primary outcome measure is the duration until first RTW. Secondary outcome measure is the severity of depressive, anxiety and somatisation symptoms in terms of respons and remission. An economic evaluation will also be performed from a societal perspective.

Discussion

In the present study, the ECO-intervention to improve sickness guidance for sick listed, workers with CMD will be evaluated for its cost-effectiveness. The ECO-intervention is aimed

at supporting the OP in the sickness guidance of workers with CMD. Existing guidelines and laws on the privacy of workers and the exchange of information will be followed.

29-apr-2014: Due to an additional sponsor (Achmea SZ), which interests are mostly fear and somatisation, the study protocol changed.

Study objective

It is expected that workers in the intervention group (ECO) return to work faster than workers in the usual care group (CAU). Furthermore, it is expected that workers in the intervention group have a larger reduction in depressive, anxiety or somatisation symptoms than workers in the CAU group. ECO is expected to be cost-effective through lower health care costs and lower productivity losses.

Study design

Follow up at 3, 6, 9 and 12 months.

Intervention

The ECO-intervention comprises a decision aid for the occupational physician (OP) and an E-health module for the depressed worker. The decision aid will support OPs in the guidance of sick-listed workers with CMD and comprises elements based on Collaborative Care, such as continuously monitoring of progress and access to psychiatric consultation. The effectiveness of ECO will be compared with that of usual care (CAU).

Contacts

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Eligibility criteria

Inclusion criteria

Workers on sickness absence between 4 and 26 weeks with common mental disorder (CMD).

Exclusion criteria

Workers who do not have sufficient command of the Dutch language to fill in the questionnaires and workers who are pregnant will be excluded, as well as workers with a legal involvement against their employer, e.g. due to a conflict at work.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2010
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

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	NL1991
NTR-old	NTR2108
Other	Zon-Mw Doelmatigheid : 80-82310-97-10094
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A