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Towards a shortened sick leave duration of employees sick-listed due to common mental disorders

Submission date	Recruitment status	[X] Prospectively registered
30/06/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/08/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/12/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
208030001

Study information

Scientific Title

Effectiveness of the guideline management of workers with common mental health problems by occupational physicians: a randomised controlled trial

Study objectives
Sick listed employees treated by occupational physicians (OPs) who are trained in and closely follow the guideline will have a shorter sick leave duration than those in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee of St. Elisabeth Hospital in Tilburg, MREC number 1162

Study design
Multicentre randomised controlled trial longitudinal design with follow up

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Sick leave due to common mental disorders

Interventions
OPs in the experimental condition are trained in the Dutch guideline 'management of workers with common mental health problems by occupational physicians'. OPs will be divided into groups of 6 - 10 OPs, and will gather for monthly meetings of approximately 1 hour, over 1 year. Using action research and focus group discussions it will be investigated which barriers OPs encounter in using the guideline. Subsequently, barriers will be explored and possible solutions will be discussed by means of a 'plan, do, check, act' cycle.

OPs from the control group provide care as usual.

The total duration of follow up will be 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Time to full return to work, defined as the number of days between the first day of sickness absence and the first day of full return to work

Key secondary outcome(s))
1. Partial return to work
2. Total days of sick leave at 12 months
3. Patient satisfaction, assessed by a short questionnaire developed for this study

4. Symptoms, measured using the 4DSQ (Terluin 2002)
Outcomes will be assessed at baseline, 3, 6 and 12 months.

Completion date
15/10/2014

Eligibility

Key inclusion criteria
1. A common mental disorder, i.e. anxiety, depression, burnout or emotional distress, is the primary reason for sick leave at the time of inclusion. Physical problems may be present, but should not cause absenteeism
2. Dutch speaking
3. Counseled by an OP that takes part in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Acute crisis or suicidality
2. Sick leave duration of less than 4 weeks, as a quick recovery of part of this group may dilute the statistical power of the study
3. Sick leave duration of more than 8 weeks, as the study aims to prevent long term sick leave

Date of first enrolment
15/10/2010

Date of final enrolment
15/10/2014

Locations

Countries of recruitment
Netherlands

Study participating centre

Tilburg University
Tilburg
Netherlands
5000 LE

Sponsor information

Organisation
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Government

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands) - (ref: 208030001)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/08/2015		Yes	No
Results article	results	01/12/2017		Yes	No
Protocol article	protocol	06/03/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes