

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

Submission date 30/06/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 11/08/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 05/12/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

15/10/2010

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

Age group

Adult

Sex

Both

Target number of participants

232

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)

Sponsor details

Laan van Nieuw Oost Indië 334

The Hague

Netherlands

2593 CE

+31 (0)70 3495111

info@zonmw.nl

Sponsor type

Government

Website

<http://www.zonmw.nl/nl/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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?
Protocol article	protocol	06/03/2013		Yes	No
Results article	results	19/08/2015		Yes	No
Results article	results	01/12/2017		Yes	No