The Cost Effectiveness of Collaborative Care for Depressive Disorder in the Occupational Health Setting

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The primary aim of the study is to evaluate the cost-effectiveness of a collaborative care model for major depressive disorder in the occupational health setting.

Ethical review	-
Status	Pending
Health condition type	Psychiatric disorders
Study type	Interventional

Summary

ID

NL-OMON30479

Source
ToetsingOnline

Brief title
CC: DOC (Collaborative Care: Depression initiative in Occupational Care)

Condition

- Psychiatric disorders

Synonym
depression, Major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Centraal Fonds RVVZ
Source(s) of monetary or material Support: RVVZ (Reserves Voormalige Vrijwillige Ziekenfonds Verzekeringen)

Intervention

Keyword: Collaborative care, Major depressive disorder, Occupational care, Problem solving treatment

Outcome measures

Primary outcome

Primary outcome measure in this study is time to return to work, as is measured by inquiry with the patient and which refers to the duration of sickness absence until return to work. Tertiairy outcome measure is the cost-effectiveness of collaborative care compared to CAU. Therefore, an estimation of the direct medical costs and the costs due to production losses (productivity costs) is made. To estimate the costs the *Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness* (TiC-P) is used. Quality of life is assessed by the EQ-5D and the SF-36.

Secondary outcome

Secondary outcome measure is reduction of symptoms as measured by the depression subscale of the *Patient Health Questionnaire* (PHQ-9). The PHQ-9 is a brief but valid instrument that scores each DSM-IV criterion of a major depressive disorder.

Additional outcome measures are as follows:

Somatoform presentation will be assessed by: (a) the Physical Complaints List (LKV), which measures the number and intensity of functional somatic complaints that a patient is experiencing 75, (b) the Whitely Index, measuring somatic amplification 76; 77, (c) the SOMS-7, measuring co-morbid somatoform disorders

78, and (d) the Illness Attitude Scale (IAS), which measures health anxiety and illness behaviour. 77

In addition to the PHQ-9, symptoms will also be assessed with: (e) the Inventory for Depressive Symptomatology Self Report (IDS-SR), measuring the severity of the symptoms of MDD as well as remission 79, and (f) the Four-Dimensional Symptom Questionnaire (4DSQ), which measures distress, depression, anxiety and somatisation, and has been developed to distinguish non-specific general distress from depression, anxiety and somatisation. 80

Concomitant symptoms of co-morbid chronic illness will be measured with: (g) the World Health Organization Disability Assessment Survey II (WHO-DAS II) 81, measuring the extent to which the patient is handicapped by MDD, and (h) the CBS list, a questionnaire developed by the Dutch Central Department of Statistics, measuring co-morbid chronic medical illness. Pain will be measured according to: (i) a Visual Analogue Scale and (j) the SF-36 Pain scale.

Patient preference will also be measured on the basis of the choices made by patients in the intervention group. Patient adherence will be assessed by means of a qualitative questionnaire in the intervention group and compared to the CAU group. 48 The treatment received in the CAU group, assessed in patients, will be measured according to the Scale Assessing Contacts between patients and practitioners. 48

The working relationship between patient and occupational physician will be assessed by means of the Patient-Doctor Relationship Questionnaire (PDRQ-9) 65 and the attitude of the occupational physician towards the treatment of MDD in general will be assessed by means of the Depression Attitude Questionnaire (DAQ). 66; 67 Work characteristics will be measured by the Job Content Questionnaire. ref Information concerning previous history of absenteeism will be acquired from the files of the occupational health service.

Study description

Background summary

Nowadays, depressive disorder is a common mental health problem, which burdens individual patients as well as society. It affects many facets of patients life, among which work. Not only is major depressive disorder (MDD) associated with absenteeism from work, absence caused by mental disorders is of longer duration on average than absence caused by physical illness. Although evidence-based treatments for MDD are available, these are applied insufficiently. Also, in most treatments occupational functioning is not a focus. Lack of coordination of care and ineffective disability management for sick listed patients may lead to long-term absenteeism and permanent disability with unnecessarily high costs. In the occupational health setting, there is a need for more efficient screening and management of MDD, with a focus on occupational functioning. The multidisciplinary collaborative care approach coordinated by a case manager has proven to be an effective model in the treatment of MDD, as appears from prior research in primary care in the USA. Hallmark of collaborative care are activated patients who take responsibility for their treatment, which could make collaborative care an effective way to deal with MDD in the occupational health setting

Study objective

The primary aim of the study is to evaluate the cost-effectiveness of a collaborative care model for major depressive disorder in the occupational health setting.

Study design

CC: DOC (Collaborative Care: Depression initiative in Occupational Care) is a randomised controlled trial in which the treatment of MDD in the occupational health setting will be evaluated in the Netherlands. The cost-effectiveness of a collaborative care model, containing adherence enhancing techniques, contracting, Problem Solving Treatment (PST), a workplace intervention, antidepressant medication, and manual guided self-help will be compared with care as usual (CAU). Patients on sick leave between 6 and 52 weeks who are diagnosed with MDD are included in the study. Patients allocated to the intervention group will receive multidisciplinary treatment based on the collaborative care framework and patients allocated to the control group will receive CAU. Care in the intervention group will be provided within a multidisciplinary team of the psychiatrist and a trained OP-care manager. The treatment is strictly and clearly separated from the sickness certification and sickness guidance, and both will be performed by different OPs. Data will be collected by means of questionnaires at baseline and at 3, 6, 9 and 12 months after baseline. Primary outcome measure is time to return to work, secondary outcome measure is reduction of symptoms. A cost effectiveness and cost-utility analysis is conducted alongside the RCT.

Intervention

A treatment of major depressive disorder according to the collaborative care model, containing a. problem solving treatment, b. an antidepressant protocol, c. contracting, d. casemanagement, e. a self-help and lifestyle manual, f. a workplace intervention

Study burden and risks

The expected risk are very little. No physiological parameters will be assessed. The control group receives care as usual. The intervention group receives only evidence-based treatment techniques. We expect that these are a supplement to care as usual. Furthermore, good results are found using the collaborative care model abroad.

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

A score of 15 or higher on the PHQ9, a short questionnaire that screens for Major Depressive Episode. The patient has to resume work for 6 to 52 weeks and has no prospect yet for work resumption.

Exclusion criteria

Patients who are suicidal, psychotic or demented, according to the company OP, will be excluded from the study (they are however referred to a doctor in case of high suicidal risk or a suggestion is given for another form of help), and also patients who are addicted to drugs or alcohol, as assessed by the MINI interview, and patients who do not have sufficient command of the Dutch language to fill in the questionnaires. Also patients who are in conflict with their employer will be excluded from the study as well as patients who are already receiving disablement insurance benefit due to MDD and patients who are pregnant. Patients with a lawsuit against their employer e.g. due to a conflict at work, will be excluded. Patients who are already receiving psychiatric treatment can be included in the study, if there is mutual agreement with their care-giver.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	116
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-03-2010
Application type:	Amendment
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	ID
ISRCTN	ISRCTN78462860
CCMO	NL13830.029.06