Do-It study
Depression & Occupation: Intervention Trial

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Primary objectives:*To evaluate the effects on labour supply (work loss days, work cut back days with lower productivity) and work productivity/functioning of psychiatric outpatient treatment (treatment as usual; TAU) vs. psychiatric outpatient...

Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders
Study type	Interventional

Summary

ID

NL-OMON30302

Source
ToetsingOnline

Brief title
DO-IT Study

Condition

- Psychiatric disorders

Synonym
major depression

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: UWV en Fonds Psychische Gezondheid (voorheen NFGV)

Intervention

Keyword: depression, labour supply, occupational therapy, work functioning

Outcome measures

Primary outcome

Primary parameters:

- work absenteism (work loss days, work cut back days)

- work productivity

- work functioning

Secondary outcome

Secondary parameters:

- psychopathology: depressive symptoms

- health related quality of life

- costs

- neurocognitive functies (concentration, memory deficits)

Study description

Background summary

Depression or Major Depressive Disorder is a mental disorder with a year prevalence of 3-5 percent and a life time prevalence of 20-30 percent for women and 15 to 20 percent for men. Depression reduces the likelihood that affected individuals will be able to participate in the labour market, either by lower workplace performance (work cut back days) or by time absent from work (work loss days). Although the effects of depression on labour market participation have been described in many ways, there are only a few studies that examined labour supply effects of interventions for major depressive disorder. During the past few years we executed a small randomized controlled trial. We studied a homogeneous sample of 62 patients with major depression who had been off from work because of depression. These patients were randomized to care as usual or care as usual plus an occupational therapy done by occupational therapist. This

study showed that the addition of occupational therapy to care as usual reduced work loss days significantly. The cost effectiveness analysis indicated that occupational therapy was cost effective. The study described in this protocol will be an improved version of the pilot project. We will improve the number of cases to increase power of the effectiveness of the occupational therapy program.

Study objective

Primary objectives:

*To evaluate the effects on labour supply (work loss days, work cut back days with lower productivity) and work productivity/functioning of psychiatric outpatient treatment (treatment as usual; TAU) vs. psychiatric outpatient treatment +occupational therapy (TAU+OT) for patients with work related depression.

*To evaluate the differential effectiveness of two types of occupational interventions (TAU+OTshort and TAU+OTlong) on work related outcome measures.

Study design

The study is a randomized controlled trial with random allocation to three conditions:
- psychiatric outpatient treatment (TAU) (n=40)
- psychiatric outpatient treatment + occupational therapy: 3 month version (TAU +OTshort) (n=60)
- psychiatric outpatient treatment + occupational therapy: 6 month version (TAU +OTlong) (n=60)

Intervention

Psychiatric outpatient treatment (TAU): patients will be treated by psychiatric residents in the outpatient department of the Mood Disorder Program according to a treatment as usual protocol.

The 6 month version (24 weeks) of OT will include 12 individual sessions, 24 group sessions and 3 follow-up sessions. The intervention focuses on coping with work related problems, mastery of work related situations, improved work functioning and the development of a work reintegration plan. The patient is directed to start working during the intervention.

The 3 month version of OT (12 weeks) will include 6 individual sessions, 8 group sessions and a work place visit. The intervention focuses on coping with work related problems, mastery of work related situations, improved work functioning and the development of a work reintegration plan. The patient may

start to work during the intervention.

Study burden and risks

The burden will consist of:

- telephone screening by physician
- 2 intake sessions by physician
- 4 neuropsychological sessions and filling out of questionnaires at researcher
- about 9 sessions for TAU
- short occupational intervention: 6 individual sessions and 8 groupsessions + workvisit
-long occupational intervention: 12 individual sessions, 24 group sessions, 3 follow-up sessions

There are no specific risks for the patient.

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

- age: 18-65 years
- diagnosis: depressive and/or dysthymic disorder (DSM IV) ;- labour effect: absenteeism or partial absenteeism (minimum of 25% absenteeism)
- duration absenteeism more than 8 weeks OR duration DSMIV diagnosis depression more than 3 months
- reintegration: possibility to return to own or new job
- relation between depressive disorder and work:
o work is one of the determinants of depressive disorder and contributes substantially (>25%) or
o depressive symptoms reduces productivity or hinders the return to work
- occupational therapy is an acceptable intervention for the patient

Exclusion criteria

- bipolar disorder
- psychotic disorder or depression with psychotic characteristics
- severe alcohol or drug misuse/alcohol or drug dependence
- severe physical problems that make participation to the study impossible
- inpatient treatment at the clinic is indicated for patient
- current participation in depression or occupational therapy cannot be discontinued
- current participation in research study that enables participation in the DO IT study

Study design

Design

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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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
CCMO	NL15357.018.06