Rehabilitation through self management for ambulant patients with chronic anxiety or depression

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To examine the cost-effectiveness of a treatment protocol focused on self management rehabilitation followed by replacement in primary care for patients with chronic depression and/or anxiety who are currently being treated in secondary care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON34330

Source
ToetsingOnline

Brief title
Self management rehabilitation

Condition

- Psychiatric disorders NEC

Synonym
Anxiety and Depression

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut
Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeraars

Intervention

Keyword: Anxiety disorder, Depressive disorder, Rehabilitation, Self management

Outcome measures

Primary outcome

Primary outcome measure will be global quality of life as measured with the World Health Organization Quality of Life instrument, Brief version (WHOQOL-BREF).

Secondary outcome

Secondary outcome measure will be cost-effectiveness. Costs will be measured using the Trimbos/iMTA questionnaire for psychiatric disorders, according to a societal perspective, thus involving medical costs and productivity costs. Furthermore, depressive and anxiety symptoms will be measured with the Patient Health Questionnaire- 9 (PHQ-9) and the Beck Anxiety Inventory (BAI) respectively. Since empowerment of patients is also an aim of this intervention, this will be assessed using the Empowermentlist.

Study description

Background summary

A significant group of patients treated in secondary care is considered to suffer from chronic depression and/or anxiety. These patients have not responded to several evidence based treatments and are currently being treated by a psychiatric nurse in "supporting contacts". This form of care is expensive and not evidence based. Treatment focused on self management rehabilitation and eventually replacement in primary care with specialty back up (collaborative care) might improve patients quality of life and be more efficient and (cost-) effective.

Study objective

To examine the cost-effectiveness of a treatment protocol focused on self management rehabilitation followed by replacement in primary care for patients with chronic depression and/or anxiety who are currently being treated in secondary care.

Study design

A randomized controlled trial. Patients will be asked to participate by their care giver (psychiatric nurse) and fully informed about the nature of the study. If they are willing to participate they will be randomized to the intervention group (self management protocol, provided by a trained psychiatric nurse, followed by replacement with specialty back-up in primary care) or the control group (continuation of usual care, with the possibility of following the self management protocol after the end of the study period).

Intervention

A self management protocol provided by a trained psychiatric nurse in secondary care. During 13 sessions in 26 weeks patients form an action plan to re-establish social contacts, improve their daily living activities, patients and their families are educated about the nature of their chronic disorder, suicidality, crises and they learn how to cope with these issues. At the end of this protocol, patients are guided in their replacement in primary care. Professionals working in primary care who will be taking over care for participating patients, will be educated about a model of collaborative care for patients with chronic depression or anxiety. Every primary care practice has to select a mental health professional (psychiatric nurse, social worker or psychologist) who functions as a care manager. This care manager works in close collaboration with the general practitioner and actively monitors functioning of the patient. The general practitioner will be responsible for prescription of medication. Both care manager and general practitioner have easy access to the advice of a consultant psychiatrist who is already familiar with the patient and are provided with a protocol for crisis situations. The process of replacement to primary care will be guided by the psychiatric nurse from secondary care. A qualitative study alongside this randomized controlled trial will be conducted to examine experiences of professionals and patients with the intervention in greater detail.

Study burden and risks

Considering care provided to the patients, no burden or risk is associated with participation. All patients receive at least usual care. For patients in the intervention group, transfer to primary care is closely monitored and if necessary, patients may return to secondary care. The burden associated with participation in this study consists solely of the conduction of a diagnostic interview (45 minutes) and completing the baseline and two follow-up

questionnaires. It takes about 30 minutes to complete this questionnaire. A small subsample of participants (approximately 15) will be invited for a qualitative interview, lasting one hour.

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

Chronic anxiety or chronic depression (> 2 years)
Have not responded to at least 1 evidence based psychological therapy and and at least 3 evidence based medication steps (checklist)
Currently receiving "supporting contacts" from a psychiatric nurse

Exclusion criteria

Bipolar disorder
Psychosis
Insufficient knowledge of the dutch language
Cognitive problems / low IQ (<80)
Dementia
Terminal disease
Alcohol or drugs addiction

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:	Recruitment stopped
Start date (anticipated):	23-11-2010
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	22-11-2010
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27623
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL33674.097.10
OMON	NL-OMON27623