Rehabilitation through selfmanagement for outpatients with chronic anxiety and depression.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27623

Source
Nationaal Trial Register

Brief title
ZemCAD (Zelfmanagement voor Chronische angst en depressie)

Health condition

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.

Sponsors and support

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

Intervention

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 costs, measured with 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 Dutch empowerment questionnaire (Boevink, Kroon, & Giesen, 2009). Possible confounders such as demographic variables and chronic diseases will be measured at baseline. Measurements will take place at baseline, after 6 months and after 18 months. Considering the qualitative study, experiences of patients will be examined using semi-structured, individual interviews, three months after ending the self management protocol.

Study description

Background summary

Rationale:

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.

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 with intervention group (self management protocol, provided by a trained psychiatric nurse, followed by replacement with specialty back-up in primary care) and the control group (continuation of usual care, with the possibility of following the self management protocol after the end of the study period). In addition to the RCT a qualitative study will be performed to gain insight in experiences of patients with the intervention.

Study population:

Patients with chronic anxiety or depression (>2 years) who have received several evidence based treatments (at least one psychological treatment and at least three medication steps), have not responded to these treatments and are currently being treated in secondary care by a psychiatric nurse in "supporting contacts".

Intervention:

A self management protocol provided by a trained psychiatric nurse in secondary care. 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.

Main study parameters/endpoints:

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 measure will be costs, measured with the Trimbos/iMTA questionnaire. Depressive and anxiety symptoms will be measured with the Patient Health Questionnaire- 9 (PHQ-9) and the Beck Anxiety Inventory (BAI) respectively. Empowerment will be assessed using the Dutch empowerment questionnaire (Boevink, Kroon, & Giesen, 2009). Measurements will take place at baseline, after 6 months and after 18 months. Considering the qualitative study, experiences of patients will be examined using semi-structured, individual interviews, three months after ending the self management protocol.

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

1. Baseline;

2. First follow-up (6 mnths);

3. Second follow-up (18 mnths).

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 patients with the intervention in greater detail.

The control group will receive care as usual.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with chronic anxiety or depression (>2 years) according to DSM-IV (MINI interview);

2. > 18 years;

3. > 2 years specialist mental healt care;

4. Currently supportive treatment;

5. Treatment resistant.

Exclusion criteria

1. Bipolar disorder;

2. Psychotic disorder;

3. Not fluent in dutch language;

4. Cognitive problems / (IQ <80);

5. Dementia;

6. Alcohol/drugs dependence;

7. Life-threatening medical condition.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-03-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34330
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3135

Register	ID
NTR-old	NTR3335
CCMO	NL33674.097.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34330

Study results

Summary results
N/A