

Collaborative Care for patients with a bipolar disorder: an effectstudy.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Manic and bipolar mood disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON38257

Source

ToetsingOnline

Brief title

Collaborative Care for patients with a bipolar disorder.

Condition

- Manic and bipolar mood disorders and disturbances

Synonym

bipolar disorders; manic depressive disorder

Research involving

Human

Sponsors and support

Primary sponsor: GGZ inGeest (Amsterdam)

Source(s) of monetary or material Support: Ministerie van OC&W, Astra Zeneca

Intervention

Keyword: bipolar disorder, Collaborative Care, Randomized Controlled Trial

Outcome measures

Primary outcome

Functioning

Quality of life

Symptomatology

Secondary outcome

Mastery

Satisfaction with care

Attitudes towards pharmacotherapy

Costs

Cargivers: Perceived burden and satisfaction with care.

Study description

Background summary

Background.

A bipolar disorder is a severe mental illness with often many consequences on daily life for patients as well as caregivers/family/friends. Treatment currently exists of pharmacotherapy, sometimes combined with psychotherapy, psycho education and teaching selfmanagement skills. A proportion of patients shows satisfying responses to this treatment, and the illness remains relatively stabile over time. Another subgroup of patients however does not respond adequately to the treatment offered. They show a rather low response to therapeutic efforts and suffer from frequent manic or depressive episodes and cognitive impairments. Often they have little social support and show low social functioning. Frequently co-morbid psychiatric and somatic disorders are present which complicate the course of the bipolar disorder. For this subgroup

of patients a specialised multidisciplinary approach is required, with optimal integration of the efforts of the different professionals who are involved in treatment and care. It is also important that the patient is actively involved in treatment, e.g. in the definition of goals of treatment and their priority. In literature such a treatment is referred to as 'Collaborative Care'. Little research has been performed on the effects of such an integrated treatment program for patients with a bipolar disorder. Bauer et al. (2006), Simon et al. (2005, 2006) en Suppes et al. (2003) researched the effects of multidisciplinary treatment methods for people with a bipolar disorder and the results are promising.

Study objective

We expect Collaborative Care to have a positive effect on functioning, amount and severity of symptoms, quality of life, costs, mastery, attitude to pharmacotherapy, and satisfaction with care. If effect of this intervention can be demonstrated we have an evidence based intervention at our disposal in which the coordinating nurse performs an important coordinating role. This intervention can be included in the existing (multidisciplinary) guidelines for treatment of bipolar disorders.

Study design

Methods

This study is a two-armed clusterrandomized clinical trial. The aim is to evaluate the collaborative care program in specialized ambulatory mental health care in the Netherlands. Collaborative Care (CC) will be evaluated against treatment as usual. CC includes tailored care, aimed at individualised goals set collaboratively by the patient, his caregiver, the nurse and the psychiatrist, who all are members of the Collaborative Team; contracting and shared decision making are core elements of CC, as well as psycho education, Problem Solving Treatment, systematic relapse prevention, monitoring of outcomes, pharmacotherapy and somatic care. Specialist nurses coordinate care and execute parts of the treatment program. Nurses and psychiatrists in the intervention group will be trained in the intervention. The intervention period is one year. Measurements will take place in the experimental and control groups at baseline, at six and at twelve month. Outcomes are symptomatology, quality of life, costs, psychosocial functioning, mastery, attitudes towards medication and satisfaction with care. Caregiver outcomes are burden and satisfaction with care.

Research questions:

1 What are the effects of a CC program performed by nurses (compared to Care as Usual) for patients with a bipolar disorder on their functioning, symptomatology, quality of life, mastery, attitude towards pharmacotherapy and satisfaction with care?

2 What are the effects of CC (compared to Care as Usual) for caregivers/family/friends of patients with a bipolar disorder on their perceived burden and satisfaction with care?

3 What is the cost effectivity of CC compared to CaU?

Intervention

The Collaborative Care Program (CCP) will be implemented in several ambulatory mental health care facilities in the Netherlands. Nurses and psychiatrist will be trained, which means that 'Collaborative Care' will be provided, tailored to the needs of the patient. Core elements of CC are:

- * Forming of a Collaborative Care Team. This team consists at least of the patient, (and preferably a family member or friend), the nurse and the psychiatrist. The team meets every three months. The primary nurse coordinates care and is responsible for continuity of care. The patient has an active role in his / her own treatment. If the patient agrees, then family members, friends or caregivers are invited to participate in treatment.
 - * Contracting. The patient is an active member of the CC-team. One important aim is to agree on the most important problems to be worked on, the related goals, and which care is needed to achieve these goals . A contract is being made, in which the problems, goals, content of treatment and care, and outcomes are elaborated.
 - * Psycho education (based on the Dutch Psycho education course, based on Hofman et al., 1992; Honig et al., 1997) adapted to the needs of patient and family.
 - * Problem Solving Treatment (Schreuders et al., 2005/2007).
 - * Monitoring and relapse prevention, by using the Life Chart Method (Leverich & Post, 1998; Kupka et al., 1996) and an emergency plan (LithiumPlusWerkgroep, 2001).
 - * Pharmacotherapy and somatic care, with continuous monitoring of the effects,
 - * Support on developing a healthy lifestyle.
- If indicated some extra interventions will be provided:
- * Activity Scheduling, if patients are prolonged depressed.
 - * Rehabilitation modules, if patients have low quality of life and minimal social participation.

Study burden and risks

We expect no negative side effects of this study.

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

Patients who are diagnosed bipolar disorder (DSM IV).
Patients aged between 18-65.
Family members or friends if the patient gives consent.

Exclusion criteria

Patients with an acute episode of mania or depression.
Patients with a stable course of the disorder.
Patients with insufficient command of the Dutch language.
Patients without an informed consent statement.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	08-07-2011
Enrollment:	206
Type:	Actual

Ethics review

Approved WMO	
Date:	15-02-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	15-11-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	28-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	26-07-2012
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
CCMO	NL32455.029.10