Collaborative Care for patients with a bipolar disorder: An effect study. Zorg in Samenwerking voor patienten met een bipolaire stoornis, een effectiviteitsonderzoek.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27569

Bron
NTR

Aandoening

Bipolar disorder
Collaborative Care
Family involvement
Randomised Controlled Trial

Ondersteuning

Primaire sponsor: GGZ inGeest/ VUMc, Amsterdam
InHolland, University for Applied Sciences, Amsterdam
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Overige ondersteuning: GGZ inGeest/ VUMc
InHolland, University for Applied Sciences
Dimence
Astra Zeneca

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Functioning;
2. Symptoms;
3. Quality of Life.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

A bipolar disorder is a severe mental health disorder with serious consequences for daily living of patients and their caregivers. Treatment as usual primarily exists of pharmacotherapy and supportive treatment. A substantial amount of the patients however does not respond well to this treatment and they suffer frequent episodes, and have persisting inter-episode symptoms, little social support and poor social functioning. Many comorbid psychiatric disorders occur, like personality disorders and substance abuse. Multidisciplinary collaboration of professionals is needed to properly combine all expertise to achieve an integrated treatment presentation. In literature ‘Collaborative Care’ is described as a method that could meet these needs. Research shows promising effects of these integrated treatment programs for patients with a bipolar disorder. In this article we describe a research protocol concerning the effects of Collaborative Care for patients with a bipolar disorder in the Netherlands.

Methods:

The research project concerns a two-armed cluster randomized clinical trial with the objective to evaluate the effectiveness of Collaborative Care (CC) in comparison with treatment as usual in ambulatory care setting for bipolar disorder. CC includes individually tailored

interventions, aimed at personal goals set by the patient. The patient, his caregiver, the nurse and the psychiatrist all are part of the Collaborative Team. Other elements of the CC-program are: contracting and shared decision making; psycho education; Problem Solving Treatment; systematic relapse prevention, monitoring of outcomes, pharmacotherapy and somatic care. Nurses coordinate and execute care. Nurses and psychiatrists in the intervention group will be trained in the intervention and execute the intervention during one year. The effects will be measured during this year at baseline and at 6 and 12 month. Primary outcomes are functioning, symptomatology, and costs. Caregiver outcomes are burden and satisfaction with care.

Discussion:

With this study we are, to our knowledge, the first to evaluate a CC program for patients with a bipolar disorder in the Netherlands. We expect to enhance quality of care for these patients.

Doel van het onderzoek

A bipolar disorder is a severe mental illness with often many consequences on daily life for patients and caregivers (family/friends). Treatment currently exists of pharmacotherapy and supportive treatment. Many patients do not respond adequately to this treatment. They 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) and Suppes et al. (2003) researched the effects of multidisciplinary treatment methods for people with a bipolar disorder and the results are promising.

Onderzoeksopzet

Measurements will take place at baseline and after 6 and 12 months of the study in patients, clinician and family of friend of the patient. The Questionnaire for Bipolar Illness, Dutch translation (QBP-NL) is used at baseline only, to measure characteristics of the bipolar disorder, the history of the illness and demographic characteristics of the patient. We will measure overall functioning with the Functioning Assessment Short Test (FAST-NL-P). This questionnaire has shown to have good psychometric proportions and has been translated in Dutch. The current severity of the disorder will be measured with the Clinical Global Impression (CGI-BP). The clinician provides his view on the severity of the symptoms of the patient, as well as detect any change in the course of the illness. This instrument is

translated and validated in Dutch. Symptoms are assessed with the Brief Symptom Inventory (BSI) which is the short version of the SCL-90, and translated and validated in Dutch. The BSI is filled in by the patient and takes about 10 minutes to complete. Depressive symptoms are measured with the Inventory for Depressive Symptoms (IDS-SR), a self report measurement containing 30 items. The psychometric proportions of the IDS-SR are excellent and a translation in Dutch is available. Manic symptoms will be assessed with the Altman Self Rating Mania Scale (ASRM). Psychometric qualities of the ASRM list are satisfying and a translation is made for this study. Course of illness and relapse will be assessed with the Longitudinal Interval Follow-up Evaluation. The research assistant will perform this by phone. Quality of life will be assessed with the World Health Organisation Quality of Life –short version (WHOQoL-Bref), which has been tested in many studies and found valid. Assessment of Needs will be measured by the Camberwell Assessment of Needs (CAN), of which validity and reliability proved to be satisfying. Mastery will be measured with the Sense of Mastery Scale. This instrument is widely used and is found valid and reliable. Satisfaction with care will be measured with a Visual Analogue Scale (VAS). We will measure costs with the Trimbos iMTA questionnaire for Costs associated with Psychiatric Illness (TiC-P). We will gather information on Attitude on Drugs with the Drugs Attitude Inventory (DAI-10), a validated list which has been translated in Dutch. Burden perceived by caregivers will be assessed with the Involvement Evaluation Questionnaire (IEQ. The IEQ is a self report list and has been validated in Dutch and widely used. Satisfaction with care will be scored by caregivers on a Visual Analogue Scale (VAS).

Onderzoeksproduct en/of interventie

Experimental condition:

The Collaborative Care Program (CCP) will be implemented in several outpatient 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:

1. 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;

2. 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;

3. Psycho education (based on the Dutch Psycho education course, Hofman et al., 1992; Honig et al., 1997) adapted to the needs of patient and family;

4. Problem Solving Treatment (Schreuders et al., 2005/2007);

5. Monitoring and relapse prevention, by using the Life Chart Method (Leverich & Post, 1998; Kupka et al., 1996) and an emergency plan (LithiumPlusWerkgroep, 2001);

6. Pharmacotherapy and somatic care, with continuous monitoring of the effects;

7. Support on developping a healthy lifestyle.

If indicated some extra interventions will be provided:

8. Activity Scheduling, if patients are prolonged depressed;

9. Rehabilitation modules, if patients have low quality of life and minimal social participation.

Control condition: Care As Usual.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients who are being treated in outpatient clinics and:

1. Who are diagnosed with bipolar disorder according to DSMIV-TR;

2. Who are aged 18-65 years;

3. If patient gives consent: One or two familymembers or friends of the patient will be included.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients in the acute phase of depression or mania (CGI-BP: degree of illness score 6 or 7);

2. Patients with such a stable course of illness (during the last six months) that low intensity of treatment suffices (2-4 polyclinical visits with a psychiatrist a year). This will be decided by the treating psychiatrist based on criteria that will be developed;

3. Patients without sufficient command of the Dutch language to be able to fill in the questionaires;

4. Patients without informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	206
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-11-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2483
NTR-old	NTR2600
Ander register	Wetenschapscommissie EMGO Amsterdam : 2010-044
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
van der Voort, TYG, van Meijel, B., Goossens, P.J., Renes, J., Beekman, A., Kupka, R.W. Collaborative Care for patients with bipolar disorder: a randomised controlled trial. BMC psychiatry, august 17, 2011.