Treatment of chronically depressed patients: a multisite randomised controlled trial testing the effectiveness of ‘Cognitive Behavioral Analysis System of Psychotherapy’ (CBASP) for chronic depressions versus usual secondary care.

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CBASP is more effective and cost-effective than usual secondary care.

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

Samenvatting

ID

NL-OMON24823

Bron
NTR

Verkorte titel
N/A

Aandoening

Treatment of Chronic depression (Behandeling van Chronische depressie).

Ondersteuning

Primaire sponsor: GGZBuitenamstel
Mentrum
PsyQ
Overige ondersteuning: ZonMw and Stichting tot Steun

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the reduction of depressive symptoms measured with the 28-item version of Inventory of Depressive Symptoms (IDS). The IDS is a measure of symptom severity in depression that has been used to assess acute and longer-term outcomes and has highly acceptable psychometric properties (Cronbach's alpha = .92). The IDS self-report version will be administered at baseline, after 8, 16 and 32 weeks and at the end of the study, at 52 weeks follow-up. Patients with a symptom reduction of 50%, measured on the IDS, can be seen as responder. Remission is defined as an IDS score of 13 or less.

In addition, the Quick Inventory for Depressive Symptomatology (QIDS), a shortened version of 16-items of the IDS, will be administered monthly during the study. Internal consistency is high for the QIDS (Cronbach's alpha = .86), and the total scores were highly correlated (.96) with the total scores of the IDS.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: 'Cognitive Behavioral Analysis System of Psychotherapy' (CBASP) is a form of psychotherapy specifically developed for patients with chronic depression. In an American study, remarkable favorable effects of CBASP have been demonstrated. However, no other studies have as yet replicated these findings and CBASP has not been tested outside the United States. This protocol describes a randomised controlled trial on the effectiveness of CBASP in the Netherlands.

Methods/design: The purpose of the present paper is to report the study protocol of a multisite randomised controlled trial testing the effectiveness of 'Cognitive Behavioral Analysis System of Psychotherapy' (CBASP) for chronic depressions in the Netherlands. In this study, CBASP in combination with medication, will be tested versus usual secondary care in combination with medication. The aim is to recruit 160 patients from three mental health care organizations (MHO). Depressive symptoms will be assessed at baseline, after 8 weeks, 16 weeks, 32 weeks and 52 weeks, using the 28-item Inventory for Depressive Symptomatology (IDS). Effect modification by comorbid anxiety, alcohol consumption, general and social functioning and working alliance will be tested. GEE analyses of covariance, controlling for baseline value and centre will be used to estimate the overall

treatment effectiveness (difference in IDS score) at post-treatment and follow up. The primary analysis will be by ‘intention to treat’ using double sided tests. An economic analysis will compare the two groups in terms of mean costs and cost-effectiveness from a societal perspective.

Intervention: The major goals of CBASP are to help patients 1) to understand the consequences of their behavior, 2) to change their patterns of coping, and 3) to improve their interpersonal skills. CBASP consists of a total of 26-30 sessions spread over a period of a year. CBASP starts with bi-weekly sessions, followed by weekly sessions up to week 16. After 16 weeks sessions will be given once every two weeks and as a maintenance treatment there will be monthly sessions of CBASP.

Discussion: The study will provide an answer to the question whether the favorable effects of CBASP can be replicated outside the US.

Doel van het onderzoek

CBASP is more effective and cost-effective than usual secondary care.

Onderzoeksopzet

Data are collected at five points in time:
1. at baseline (T0);

2. after 8 weeks of treatment (T1);

3. after 16 weeks of treatment (T2);

4. after 32 weeks of treatment (T3);
5. at the endpoint, after 52 weeks of treatment (T4).

The Quick Inventory of Depressive Symptomatology self-report will be assessed monthly. Table 1 summarizes the measures that are used at each point. The assessments will be performed by an experienced research nursing staff. At baseline and endpoint there will be, besides written questionnaires, a face-to-face interview, the three assessments in between consist of written questionnaires only. The research nursing staff from the three participating organizations will participate in a two-day training course to make sure the measures are conducted the same way at the different locations.

Onderzoeksproduct en/of interventie

CBASP;

The central idea of CBASP is that chronically depressed patients fail to recognize the connection between their behavior and interpersonal/environmental consequences. In other words, they do not grasp their own contribution to the life difficulties they encounter. The major goals of CBASP are to help patients:

1. to understand the consequences of their behavior;

2. to change their patterns of coping;
3. to improve their interpersonal skills.

CBASP is highly structured, focuses on teaching social problem skills, and makes use of regular homework assignments. The main focus is on interpersonal problems with significant others, but also in the therapist-patient relationship. The relationship with the therapist is used as a tool to help patients to become more aware of their impact on others and to distinguish between adaptive and maladaptive relationships.

CBASP consists of a total of 26-30 sessions in a period of a year. CBASP starts with bi-weekly sessions in the first 4 weeks followed, in principle, by one session per week from week 5-16. If establishing the therapeutic relationship proves particularly difficult, the two-weekly sessions can be prolonged for four more weeks. After 16 weeks (16-20 sessions), 4 sessions will be given once every two weeks during weeks 17-25, and as a maintenance treatment there will be 6 monthly sessions of CBASP during weeks 26-52.

Treatment as usual

Within the three sites, treatment as usual is based on the existing Dutch multidisciplinary guidelines (2005) for depression (15). This means that, besides optimal medical care, treatment as usual can consist of evidence-based psychotherapies, such as Cognitive Behavioral Therapy, Interpersonal Psychotherapy, or Short Psychoanalytic Supportive Psychotherapy (de Jonghe BJP 2004). Other interventions that may be part of the treatment offered for chronically depressed patients are supportive or structured activities and treatments that focus on relaxation, assertiveness, running, or other tasks. The treatment package received by patients in the treatment-as-usual condition will be registered throughout the study.

Pharmacotherapy

In both conditions medical treatment will be given, consisting of guideline' driven antidepressant drug treatment (15). The pharmacotherapy will be supported by 'clinical

management' (19): brief sessions in which patients will be informed about the importance of adherence and the effects and side effects of medication. The psychiatrist will change the dose or medication when necessary. The use of medication (name, dose given and blood level were available) will be registered for all patients participating in the study. Patients who refuse to use medication will not be excluded from participation in the study, because CBASP has also been found to be effective as a monotherapy for chronically depressed patients, although not as effective as when it is used in combination with medication(11).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients (aged 18-65) are eligible to participate if their main diagnosis is a chronic form of depression according the DSM-IV criteria:

1. a chronic depressive disorder (i.e. existing for longer than 2 years);

2. a depressive disorder superimposed on a dysthymic disorder;

3. a recurring depressive disorder which, in the past 2 years, never fully remitted between the episodes.

The Mini International Neuropsychiatric Interview plus (M.I.N.I. plus), a structured diagnostic interview developed in 1990 by psychiatrists and clinicians in the United States and Europe for DSM-IV and ICD-10 psychiatric disorders, will be used to assess chronic depression (16, 17). In addition, the level of symptom severity should be moderate to severe, as expressed as a score of 22 or more on the 28-item Inventory for Depressive Symptomatology (IDS) (18).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients are excluded from the study if:

1. they suffer from one (or more) of the following disorders: a psychotic disorder, bipolar disorder, organic brain syndrome, severe substance or alcohol dependence, or a severe borderline, schizotypical, or antisocial personality disorder;

2. high risk of suicidality;

3. they do not have sufficient command of the Dutch language necessary to participate in the study.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2006
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-10-2007
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	NL1057
NTR-old	NTR1090
Ander register	ZonMw : 100-003-022
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A