The effectiveness of "Cognitive Behavioral Analysis System of Psychotherapy" (CBASP) for Chronic Depressions.

Published: 14-12-2006
Last updated: 20-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON30104

Source
ToetsingOnline

Brief title
The effectiveness of CBASP for Chronic Depressions.

Condition

- Mood disorders and disturbances NEC

Synonym
chronic (DSM-IV), Depessive disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Buitenamstel (Amsterdam)

Source(s) of monetary or material Support: ZonMw/praktijk zorgprojecten Geestkracht,stichting tot steun VCVGZ

Intervention

Keyword: Chronic Depressions, Cognitive Behavioral Analysis System of Psychotherapy (CBASP)

Outcome measures

Primary outcome

OUTCOME:

All measures of outcomes are widely used internationally, are reliable and valid, also for usage in the Netherlands. Measurements take place at 0 weeks (pre-test) and after 12 weeks (post-test). In addition a half-year follow-up will take place after 26 weeks. The inclusion period will extend over a period of a year. The primary measure of outcomes is the IDS-C, with which the reduction in the seriousness of the depression can be measured. Patients with a complaint reduction of 50%, measured on the IDS-C, can be seen as responder.

Secondary outcome

Secondary measures of outcomes are the EUROquol, which measures the degree of limitation and quality of life (Dolan, 1997); the CSQ-8 which measures patient satisfaction with the interventions (de Brey, 1983); TIC-P, which tracks both absenteeism levels and the utilization of care services (www.imta.nl/publications/0261.pdf;) and health care consumption will be kept up with a diary.

The measurements will be performed by research nursing staff who are blind to the treatment condition of the included patients.

Study description

Background summary

The proposed research project fits in well with the 'Early evaluation of medical innovation' sub-programme of the Efficacy Study. For it concerns the application of a new intervention that has proved its value elsewhere (in the USA) but is not yet applied anywhere in the Netherlands. It focuses on the effectiveness of an innovative intervention that is relevant for the treatment of patients affected by a chronic mood disorder. Chronic depression is a big health problem, both from a patient perspective and from a social perspective. Patients with chronic depression are amply represented within mental health populations and healthcare professionals experience the treatment of these patients as difficult and often unsatisfactory because the existing treatment protocols fall short of these patients' needs.
Most intervention research with this specific group of patients relates to medicinal treatments. These were shown to be effective if optimally carried out, though the remission percentages remained low (Keller et al., 1998). However, an optimal approach is rarely achieved in practice. The willingness to accept and comply with medicinal treatment is often low: an estimated fifty per cent of the patients fail to follow the recommended therapy (Spijker et al., 1998). This supports the idea that, both from a care and patient perspective, there is a need for effective psychotherapeutic treatment for chronic depression. Though little is known about the (cost-)effectiveness of different forms of psychotherapy with chronic depression, CBASP has been shown to offer clear added value in the treatment of this group of patients.
Research into the (cost-)effectiveness of CBASP can make an important contribution to the improvement of care for chronic depressive patients in the Netherlands. According to the American research results (Keller et al., 2000), 73% of these patients can be effectively treated if CBASP is combined with medicinal treatment. CBASP can also be an alternative for patients who are not motivated for or refractory to medicinal treatment. The application of CBASP is innovative for the Dutch situation as this form of therapy is not yet applied here.
One unique feature of CBASP is that this treatment is 'designed' for chronic depressive patients (McCullough, 2000). The complaints and behavioural pattern that are characteristic for chronic depressive patients are explained on the basis of an explanatory model that was specifically designed for these patients. The central notion is that patients with chronic depression are extremely self-absorbed and withdraw from social interactions. Partly for this reason they are not receptive to the usual cognitive-behaviour and interpersonal therapies, which consequently tend to produce unsatisfactory results with these patients. Both the patients and the therapists feel powerless as they are unable to break the cycle of hopelessness. With the treatment model of CBASP the therapist is taught specific techniques to break

through the pattern of social withdrawal. The therapist's first step is to build a relationship with the patient. This patient-therapist relationship is pivotal to the treatment. The intensive bond that is built up with the patient gives the therapist a basis for adopting an actively confrontational stance. In this way the therapist offers the patient insight into the characteristics of chronic depression and the accompanying behaviour, as also occurs in the therapy sessions, and teaches the patient to change dysfunctional interaction patterns. In addition, CBASP makes extensive use of normal cognitive-behavioural therapeutic and interpersonal techniques, but only after a basis for growth has been created through the intensive patient-therapist relationship.

The results of this study will make it clear whether CBASP may also lead to more (cost-)effective care in the Netherlands for chronic depressive patients. Insofar as we know, no other study into CBASP is currently being conducted in the Netherlands

Study objective

The project aims to establish whether CBASP can be a good addition to the current range of treatments for chronic depressive patients in second-line mental healthcare services. This group of patients is amply represented within institutions for outpatient mental healthcare and the normal range of healthcare services often falls short of their needs.
A randomized clinical trial alongside an economic evaluation is planned, addressing the following research questions:
1. Is CBASP CAU more effective than CAU regarding disability, quality of life and healthcare utilization?
2. Is CBASP more cost-effective than CAU alone?

Study design

STUDY DESIGN:
The (cost-)effectiveness of CBASP will be studied in a randomized clinical trial, where CBASP is compared with the normal second-line care for patients with chronic depression.

Intervention

INTERVENTIONS:
After the screening, all patients will be allocated at random to CBASP or to normal care. CBASP consists of 16-20 sessions spread over 12 weeks; two sessions per week in the first 4 weeks followed, in principle, by one session per week through to week 12. If establishing the therapeutic relationship proves particularly difficult, the two-weekly sessions can be continued longer. The work will be performed on the basis of the CBASP protocol. The exercise

book for therapists will be translated into Dutch (McCullough, 2001). All participating therapists will be trained by McCullough. In the CBASP condition the existing use of anti-depressants will be continued. Within the control condition, the existing treatment will be continued.

Study burden and risks

The burden of participation for the patients will be five hours of extra work. These five hours consist of five measure moments, where the patient has to fill in questionnaires.

Contacts

Public
GGZ Buitenamstel (Amsterdam)

A.J. Ernststraat 887
1081 HL Amsterdam
NL
Scientific
GGZ Buitenamstel (Amsterdam)

A.J. Ernststraat 887
1081 HL Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients (aged 18-65) can take part if they meet the DSM-IV criteria for: a) a chronic (i.e. existing for longer than 2 years) depressive disorder or b) depressive disorder superimposed on a previus dysthymic disorder or c) a recurring depressive disorder which, in the past 2 years, never went into full remission between several episodes.

Exclusion criteria

Psychotic disorder, bipolar disorder, organic psychosyndrome, dependence on drugs or alcohol, and serious personality disorder (schizotypical, antisocial, borderline).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	165
Type:	Anticipated

Ethics review

Approved WMO Date:	14-12-2006
Application type:	First submission

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	NL13765.029.06