Cognitive behavioural group therapy for bipolar disorder: a case series design.

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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-OMON41633

Source
ToetsingOnline

Brief title
Group CBT for bipolar disorder: a case series design.

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
bipolar (I, II) disorder, manic-depression

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Vanuit de deelnemende organisaties.

Intervention

Keyword: bipolar, case series, cognitive behavioural therapy, group

Outcome measures

Primary outcome

Group CBT as an adjunctive intervention for bipolar disorder is effective in:

• Primary outcomes:

o Decrease in dysfunctional attitudes

o Increase in sense of mastery over life outcomes

Secondary outcome

• Secondary outcomes:

o Decrease in (subsyndromal) symptoms of bipolar disorders

• Tertiary outcomes:

o Decrease in comorbid physical en psychological symptoms

o Improvement of psychosocial functioning

o Increase in quality of life

Study description

Background summary

Aanpassing nav vraagbrief METC dd 9-4-2014:
British and Dutch guidelines for bipolar disorder (NICE, 2006; Nolen et al, 2008) emphasize the use of CBT as a psychological intervention (amongst others) in the treatment of bipolar disorders, but as is described in national and international guidelines relatively little research is conducted in this area (APA, 2010; Hirschfield, 2005; NICE, 2006; Nolen et al, 2008). To our knowledge, no Dutch CBT protocol for bipolar disorders is validated in research, or even considered evidence-based practice. Moreover, CBT is mostly administered as individual, not group treatment. Our objective in this research is to conduct a preliminary study to generate hypotheses on the efficacy of a

cognitive behavioural group intervention for bipolar disorder, which can be tested in further analytic studies.

Study objective

The aims of this research are to estimate the efficacy of a relatively brief group CBT for bipolar disorders, by following the level of mood symptoms over time, and by assessing whether changes in dysfunctional attitudes and sense of mastery over life outcomes occur. A further aim of the current study is to evaluate changes in comorbid physical and psychological symptomatology, psychosocial functioning and quality of life.

Study design

In this study, a case series design will be used, with an A-B multiple baseline design, involving a baseline, a treatment and a follow-up phase.
When being enrolled in this study, participants and therapists will complete a number of questionnaires and interviews. From then on, participants will start charting or monitor their mood. At the start of the intervention, participants will complete a battery of questionnaires. In addition, they will continue to monitor their mood during the intervention. Directly after the intervention phase, participants will complete the same battery again. Therapists will assess the severity of the overall illness, manic and depressive symptoms weekly during the intervention phase. Participants will monitor their mood until follow-up after the intervention is finished. At follow-up at 2 and 12 months, participants will complete the battery of questionnaires again.
In each of the participating locations, the CBT group will take place one or two times annually. The period of data gathering will be from now on.

Intervention

We will use a Dutch group CBT protocol for bipolar disorders.

Study burden and risks

Aanpassing nav vraagbrief METC dd 18-6-2014:
The burden for participants in this research will mainly consist of repeatedly completing questionnaires. In mental health, it has become common practice and even obligatory to monitor effects of treatment (routine outcome monitoring) to be able to evaluate the efficacy of individual treatment, psychological treatments or teams, to conduct research and to answer for results to other parties such as management, health insurance companies and government (Buwalda et al, 2011; Van Hees et al, 2011). In this study, a substantial part of the instruments is frequently used in treatment as usual in routine outcome measurement and diagnostics, only some of the instruments are added for the gathering of data fit this specific research.

We expect no risks for participants as a result of participating in this research and the intervention.

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

Aanpassing nav vraagbrief METC dd 9-4-2014:
Inclusion criteria in this study are:
- >= 18 years of age,
- A primary diagnosis of DSM-IV bipolar I or II disorder,
- Euthymic state or only mildly depressed or hypomanic at the start of the intervention,
- >= 1 episode in the past 18 months,
- Lifetime <= 12 previous episodes (since CBT has proven to be less effective in those with more than 12 previous episodes (Scott et al, 2006).

- Receiving treatment as usual.

Exclusion criteria

Participants will be excluded from this study if the presence of comorbid conditions is obviously impeding their ability to participate in the intervention (for example: substance abuse, mental retardation, organic brain disorder, the presence of a concurrent significant medical condition, severe suicidality or psychosis). Furthermore, participants will be excluded if they are currently receiving other psychological treatments.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-08-2014
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	24-07-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-12-2015

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL47889.060.14