Reducing relapse and recurrence in depression with continuation Cognitive Therapy: a randomized controlled trial.

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

Summary

ID

NL-OMON40027

Source
ToetsingOnline

Brief title
Relapse prevention in depression.

Condition

- Mood disorders and disturbances NEC

Synonym
depressive disorder; depression

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cognitive Therapy, health economics, Major Depressive Disorder, prevention, randomized controlled trial, recurrence

Outcome measures

Primary outcome

The primary outcome measure is the cumulative proportion of

relapses/recurrences in a survival-analysis over a follow-up period of 15

months after the start of the preventive therapy as measured with the

*Structural Interview for DSM-IV (SCID) using the Longitudinal Interval

Follow-up Evaluation (LIFE).

Secondary outcome

The secondary outcome variables are:

1. the severity of depressive symptoms as measured with the 'Inventory of

Depression Symptomatology' (IDS-SR), and the *Hamilton Depression Rating

Scale* (HDRS),

2. well-being, quality of life as measured with (EQ-5D),

3. social and interpersonal functioning as measured with the *Inventory of

Interpersonal Problems* (IIP),

4. coping styles as measured with the *Utrecht Coping List* (UCL)

5. experienced negative life events as measured with the 'Brugha Questionaire'

(Brugha)

6. personality disorder symptomatology as measured with the *Personality

diagnostic questionnaire-revised* (PDQ-R)

7. level of psychological mindfulness as measured with the *Psychological

Mindfulness Scale* (PMS)

8. sense of mastery as measured with the *Mastery scale*

9. consumption of mental health care and degree of work absence as measured with the *Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness* (TIC P)

10. identification of potential mediators and mechanisms of change using: a. coping styles as measured with the subscales *Active coping* and *Avoidance* of the *Utrecht Coping List* (UCL), b. social support as measured with the *Sociale Steun Lijst * Interacties* (SSL-I), c. acceptance and action as measured with the *Acceptance and Action Questionnaire* (AAQ), d. assessment of outcome as measured with the *Outcome Rating Scale* (ORS), e. the client*s perspective of the alliance with the therapist as measured with the *Session Rating Scale* (SRS), f. the severity of depressive symptoms as measured with the *Beck Depression Inventory* (BDI), g. working alliance as measured with the *Werk Alliantie Vragenlijst* (WAV-12), h. the intensity of dysfunctional attitudes as measured with the *Dysfunctional Attitude Scale* (DAS-17), i. the need for affiliation as measured with the *Affiliatie Lijst*, j. experienced daily stressors as measured with the *Daily Hassles Questionnaire*, k. positive and negative affects as measured with the "Positive Affect Negative Affect Scale" (PANAS).

Study description

Background summary

Major depressive disorder (MDD) is one of the most prevalent of the psychiatric disorders and is projected to rank second on a list of 15 major diseases in terms of burden in 2030. The major contribution of MDD to disability and health care costs is largely due to its highly recurrent nature. Acute phase treatment with Cognitive Therapy (A-CT) is a well-studied and evidence-based psychological intervention (e.g. Beck, 2005; Vittengl ea., 2007). Although two-thirths of all patients respond to A-CT, a sizable number will experience a return of symptoms after treatment (Fava et al., 2004; Driessen & Hollon 2011). Reported relapse and recurrence rates for high risk groups rise up to 60-70% recurrence over 2 year (Vittengl et al., 2007; Bockting et al., 2009). Apart from the number of previous episodes, residual symptoms are risk factors for recurrence
(Fava et al., 2004; Judd et al., 1998).

Optimizing long term outcomes is thus an important goal in the treatment of MDD, especially for well known high risk groups, i.e. patients with multiple previous episodes and/or residual symptoms. Providing Continuation Preventive Cognitive Therapy (C-PCT) seems promising, especially in high recurrence risk patients (for a meta analysis Vittengl et al., 2007; Jarrett et al., 2001).

Previous studies indicated that responders to A-CT already have a reduced relapse/recurrence risk compared with other forms of acute phase depression treatments (Vittengl et al. 2007). Therefore the objective of this study is to examine the surplus value of C-PCT on relapse/recurrence for patients who responded to A-CT.

Study objective

The main objective of our study is to evaluate in a randomized clinical trial the long-term clinical effectiveness of brief C-PCT in high risk recurrently depressed patients (responding to A-CT), compared with care-as-usual (monitoring). High risk patients (two or more MDD episodes and a HRSD<14) will be allocated at random to either care-as-usual or brief C-PCT. The intervention will last 8 sessions in 12 weeks. Assessment of outcome variables will be performed at the start of the intervention and 3, 6, 12, 15 months later. The primary objective of this study is to evaluate in a randomized controlled clinical trial the long-term clinical effectiveness of brief C-PCT on relapse/recurrence over 15 months, in high risk recurrently depressed patients (responding to A-CT), compared with care-as-usual (monitoring). Baed on previous studies we hypothesize that C-PCT will reduce the change of relapse/ recurrence 20%, during a follow up period of 15 months. The primary outcome measure is the cumulative proportion of relapses/recurrences in a survival-analysis over a follow-up period of 15 months after the start of the preventive therapy. Secundairy objectives are to determine mediators, moderators and a cost effectiveness evaluation.

Secondary objectives of this study are:

1. The effect of C-PCT on the severity of depressive symptoms, quality of life, social and interpersonal functioning, coping style.
2. Identification of moderating effects of experienced negative life events, personality disorder symptomatology, psychological mindfulness, mastery.
3. Identification of mediating effects of coping style, social support, acceptance and action, outcome, alliance with the therapist, depressive symptoms, working alliance, dysfunctional attitudes, need for affiliation, daily stressors, positive and negative affects.
4. Cost effectiveness of C-PCT compared with CAU.

Study design

Patients who during the acute phase of their last episode received CT at the Arkin Mental Health Care Institute of GGZ Ingeest wil be recruited. Patients who give informed consent will be randomly allocated to a control condition or an experimental condition. Patients in the control condition receive care as usual (CAU). CAU consists of the usual care that patients receive in primary care (and partially in secondary care) after treatment for acute depression. CAU typically consists of anti-depressant maintenance medication, or no treatment at all. CAU is in most cases provided by the general practitioner. Patients in the experimental condition receive, in addition to care as usual, 8 sessions of C-PCT. At baseline and 3, 6, 12 and 15 months measurements will be performed to evaluate the effectiveness of C-PCT in comparison to care as usual. After each C-PCT session a short questionnaire will be assessed in order te study working mechanisms (mediators) of C-PCT.

The time-Schedule of this study is; recruitement: months 1-36, C-PCT intervention: months 2-39, follow-up assessments: months 2-51, data-analyse en reporting: months 52-54.

Intervention

Short-term continuation PCT (C-PCT) consist of 8 sessions that is offered as sequential treatment after response to A-CT. CT is directed at the identification of maladaptive cognitions and the development of a personal prevention strategy. C-PCT (Bockting et al., 2009) is an adapted type of cognitive therapy specifically developed to prevent relapse in recurrent depression and adapted to remitted patients. A specific manual for the client and therapist has been published describing the structure of the treatment and the intervention used is available (Bockting et al., 2009). Unlike CT for acutely depressed patients, C-PCT is not primarily directed toward modifying negative thoughts. Instead, it starts with the identification of negative thoughts and dysfunctional attitudes, aided by a self report questionnaire with examples of attitudes and specific techniques. The focus of treatment is then directed on changing these attitudes using different cognitive techniques. In addition specific attention will be paid to enhancing the memory and retrieval

of positive experiences and making a person prevention plan.

Study burden and risks

Burden: Patients participating in this study, and allocated to the experimental condition receive 8 session of a psychosocial intervention of 1 hour each. After each session patients will be asked to fill in several short questionnaires which will take 15 minutes. Patients allocated to the control condition will fill in the same questionnaires twice witch will take 20 minutes. All participants will be asked to fill in 5 questionnaires each lasting 60 minutes. All participants will undergo an interview at baseline and at 15 months witch will take 60 minutes. The total burden for patients in the control condition is 7.3 hours during the total follow up time of 15 months. The total burden for patients in the experimental condition is 14.6 hours during the total follow up time of 15 months. This includes 8 hours of psychosocial intervention.

Risks: We see no risks for participants.

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

1. Two or more previous depressive episodes,
2. In remission according to DSM-IV criteria,
3. A current score of <14 on the Hamilton Rating Scale for Depression,
4. Received CT during the acute phase of the last episode.

Exclusion criteria

1. Current mania or hypomania or a history of bipolar illness,
2. Any psychotic disorder (current and previous),
3. Alcohol or drug misuse,
4. Predominant anxiety disorder,
5. Insufficient mastering of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2011
Enrollment:	214
Type:	Anticipated

Ethics review

Approved WMO Date:	30-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-06-2014
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	NL34721.097.10
Other	NTR registratienummer: 2599