Schema-Focused Therapy for Chronic Depression: Efficacy and Mechanisms of Change

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

Summary

ID

NL-OMON34720

Source
ToetsingOnline

Brief title
Schema-Focused therapy for Chronic Depression

Condition

- Mood disorders and disturbances NEC

Synonym
Despondency, Gloominess

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic Depression, Mechanisms of Change, Schema-Focused Therapy

Outcome measures

Primary outcome

The main outcome variable is change in severity of depressive symptoms during the intervention phase as assessed by the Beck Depression Inventory II (BDI-II) and the presence or absence of chronic major depressive disorder as assessed by the Structured Clinical Interview for DSM-IV (SCID 1) at the end of treatment and at 12 months follow-up.

Secondary outcome

Further variables in this study are:

Cognitive measures: Attributional Styles Questionnaire (ASQ), Core beliefs Visual Analogue Scale (VAS), Dysfunctional Attitudes Scale (DAS), Schema Questionnaire (SQ), Schema Mode Inventory (SMI).

Interpersonal Measures: Inventory of Interpersonal Problem *Circumplex (IIP-C), Relationships Scales Questionnaire (RSQ).

Therapeutic Alliance: Working Alliance Inventory Client Version (WAI-C).

Measures of Self-Esteem: Rosenberg Self-Esteem Scale (RSE), Single Category Implicit Association Test (SC-IAT).

Emotional Experiences: Positive and Negative Affect Scale (PANAS).

Other Measures: Blood oxygen level dependent (BOLD) response (measured using fMRI), Structured Clinical Interview for DSM-IV Axis II (SCID2), Childhood Trauma Questionnaire (CTQ).

Study description

Background summary

Chronic major depressive disorder (MDD) is a relatively common mental illness that represents a significant burden on the health care system. Compared to episodic forms of depression, chronic MDD is associated with higher economic costs, has a stronger impact on the quality of life, and results in more suicide attempts.
Response rates to available treatments for chronic forms of depression are low and effects of treatment attempts are only maintained as long as treatment is continued. One reason for this might be that current treatments for chronic depression leave the underlying vulnerability to depression largely untouched. In this light we propose schema-focused therapy (SFT) as a novel treatment approach to chronic MDD.

Study objective

Our primary aim is to test whether SFT is a suitable and effective treatment for chronic depression in terms of acute effects and the prevention of early relapse.
Our secondary aim is to identify the underlying mechanisms of change in SFT that lead to recovery from depression and the prevention of future relapse.

Study design

The present study is an intervention study with multiple baselines and measurement occasions. We implemented a non-concurrent single-case series A-B-C design with multiple quasi-randomized baselines across participants and 12 months follow-up. Phase A in this study is a baseline phase with a minimum duration of 6 weeks and probably longer, depending on the waiting time at the Riagg Maastricht. Phase B is a 12 week exploration phase during which the case-conceptualization will be done and treatment goals will be set. Phase C is the intervention phase wherein patients will receive SFT during a period of

approximately 18 months. In total this study will last between 2 and 3 years for each individual participant, depending on the individual progress in therapy.

Intervention

All patients in this study will receive 25 to 75 once weekly sessions SFT over the course of 18 months, depending on the individual progress in therapy. SFT is a novel treatment approach to chronic, lifelong problems that incorporates cognitive, behavioral, experiential and psychodynamic elements and techniques.

Study burden and risks

Participants in this study will be asked to regularly complete a number of questionnaires, complete a clinical interview at three moments in time, and to complete a small computer task five times. Completion of the weekly questionnaires will take about 5-10 minutes per week and completion of the monthly questionnaires about 1 1/2 hours per month. The computer task will take about 20 minutes to complete and the clinical interview between 1 and 2 hours. Questionnaires will be obtained regularly during the baseline phase A, the exploration phase B and the intervention phase C. During follow-up the most important outcome measures will be obtained on a monthly basis which will take about 5-10 minutes per month. At 12 months follow-up participants will be asked to visit the Riagg Maastricht once in order to complete the clinical interview which will take between 1 and 2 hours.
Participants will also be asked to complete a self-reflection task while undergoing functional magnetic resonance imaging (fMRI) at two time points. The first fMRI session will be conducted before the start of the intervention and the second fMRI session at the end of the intervention phase. Each session will take about 45 minutes to complete. During both sessions participants will be asked to complete a short self-reflection task. During the second a mood induction procedure will be used in addition to the self-reflection task. This standardized procedure will consist of mood suggestive music in combination with autobiographical recall (10 minutes).

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

Diagnosis of current chronic major depressive disorder (meeting criteria of major depressive disorder for at least 2 years); Beck Depression Inventory II score at screening ><=20; age range 18-65, can understand and speak the Dutch language.

Exclusion criteria

Acute suicide risk; the depression is due to a physical illness, medication intake, substance or drug abuse; comorbid autism spectrum disorder; presence of any cluster A or cluster B personality disorder.

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):	22-10-2010
Enrollment:	27
Type:	Actual

Ethics review

Approved WMO

Date:	06-09-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT01153867
CCMO	NL31871.068.10