Schema-ECT: A novel treatment for severe depression

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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-OMON41362

Source
ToetsingOnline

Brief title
Schema-ECT

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, Major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: Depression, ECT, Reconsolidation, Schema

Outcome measures

Primary outcome

Treatment efficacy as measured with the Hamilton Rating Scale for Depression (HAM-D; 17-items). Response is defined as a 50% reduction and remission as a score <=7. The influence on negative schemas is measured with the Dysfunctional Attitude Scale (DAS), the Automatic Thoughts Questionnaire (ATQ), and the Self-Referent Encoding Task (SRET).

Secondary outcome

-Hippocampal magnetic resonance spectroscopy (MRS)

-Structural connectivity using diffusion tensor imaging (DTI)

-Functional connectivity using functional magnetic resonance imaging (fMRI)

-Dopaminergic (dys-)function measured by a functional MRI of a probabilistic reward-related learning task (UMCG only)

-Biomarker levels determined from blood samples

Study description

Background summary

Electroconvulsive therapy (ECT) is often considered a last treatment option for otherwise treatment resistant depression. Unfortunately, approximately 50% of patients do not respond sufficiently (Heijnen et al., 2010). Furthermore, of the patients who respond initially, 40-80% relapse within half a year (Sackeim et al., 2001). We hypothesize that suboptimal efficacy of ECT could be due to insufficient modulation of negative cognitive schemas, which are relative stable representations of prior knowledge and experiences. These negative schemas distort the perception of new experiences in a maladaptive manner, and

focus one*s thoughts on negative aspects of oneself. Cognitive theories of depression hold that these negative schemas play an important role in the development, maintenance and recurrence of depression (Beck and Clark, 1988). We recently found that memories can be weakened by applying ECT shortly after reactivation of a memory (Kroes et al., 2013). This suggests that reactivation of negative schemas just prior to ECT may also weaken those schemas. According to the cognitive theory of depression this will lead to the recovery from depression and will additionally reduce the risk to relapse, but this has not yet been investigated. Here, we aim to investigate the efficacy of *schema-ECT* and hypothesize that repeated reactivation of depressive schemas prior to ECT weakens negative schemas, increases the efficacy of the ECT course, and reduces the relapse rate after the reduction of the ECT session frequency or discontinuing ECT. In addition to our main aim, we will investigate how the response to ECT influences brain function and structure using MRI and MRS to gain further understanding of the neural mechanisms that underlie the ECT response and in addition to the MR scans take blood samples from the venous catheter to analyze whether biomarkers can predict treatment response.

Study objective

Our primary objectives are to determine whether schema-ECT increases the remission rate of a course of ECT, reduces the relapse rate, and weakens negative schemas. Our secondary objectives are to assess the neurobiological mechanisms underlying the response to ECT using neuroimaging and blood biomarkers and to identify neurobiological biomarkers that can predict treatment response.

Study design

A randomized controlled trial (RCT) is used to determine schema-ECT efficacy. The influence of response to ECT on neuroimaging and blood biomarkers will be determined using a longitudinal, parallel group design, for which we will compare ECT responders to non-responders.

Intervention

Patients will be randomized to schema-ECT or control-ECT, stratified for research center. Schema-ECT consists of reactivation of depressive schemas using the arrow-down technique that is used in cognitive-behavioral therapy (CBT). In the control condition, patients will be interviewed about details that are also of clinical relevance but are not expected to activate depressive schemas (e.g., their medical record, diet, exercise). ECT is performed according to the national guidelines, which consists of a minimum of 6 biweekly sessions until remission or a plateau in response is achieved.

Study burden and risks

The burden of ineffectively treated depression is high. The burden of ECT is considerable but is warranted because of successful treatment, and its risk can be considered negligible. Importantly, only the regular ECT-population will be recruited. The additional burden for participating in this study is minimal and the additional risk can be considered negligible. Because the treatment under investigation is expected to increase the efficacy of ECT, patients may directly benefit from participating in this study. The additional burden for participating in the neuroimaging study can be considered minimal, and the additional risk for eligible candidates is negligible. The additional burden for blood sampling from the venous catheter that is already placed as part of the ECT procedure can be considered minimal and the risk negligible.

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

-Major depressive disorder (MDD) without psychotic symptoms
-Clinical indication for ECT
-18-70 years of age

Exclusion criteria

-Bipolar disorder, schizophrenia, primary alcohol or drug abuse, or any cognitive disorder

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2014
Enrollment:	98
Type:	Actual

Ethics review

Approved WMO

Date:	09-12-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	20-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-12-2015
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

ID: 26071
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47246.018.13
OMON	NL-OMON26071