Schema-ECT

Gepubliceerd: 14-02-2014 Laatst bijgewerkt: 15-05-2024

We recently found that memories can be weakened by applying electroconvulsive therapy (ECT) shortly after reactivation of a memory (Kroes et al., 2014). This suggests that reactivation of negative schemas just prior to ECT may also weaken those...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26071

Bron
NTR

Verkorte titel
Schema-ECT

Aandoening

Depression, ECT, reconsolidation

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: Hersenstiching

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Hamilton Rating Scale for Depression (HAM-D) scores
• Time to relapse/recurrence

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 whether the clinical response to ECT response is associated with changes in neurobiological biomarkers using neuroimaging scans and blood samples obtained from the venous catheter, and whether these biomarkers at baseline can predict treatment response (van Waarde et al., submitted).

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 identify neurobiological biomarkers that predict and are associated with treatment response.

Study design: A randomized controlled trial (RCT) is used to determine schema-ECT efficacy. Neuroimaging and blood biomarkers will be associated with changes in clinical variables.

Study population: 98 patients with a primary diagnosis of major depressive disorder (MDD) and an indication for ECT between 18-70 years of age. Eligible candidates for MRI will be asked to participate in the neuroimaging experiment.

Intervention (if applicable): 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.

Main study parameters/endpoints: 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). Neuroimaging biomarkers are hippocampal magnetic resonance spectroscopy (MRS), diffusion tensor imaging (DTI), and resting-state functional magnetic resonance imaging (fMRI). Blood biomarkers will be determined from blood samples obtained from the venous catheter that is placed for anaesthesia induction during the treatment phase or venapuncture at follow-up.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Doel van het onderzoek

We recently found that memories can be weakened by applying electroconvulsive therapy (ECT) shortly after reactivation of a memory (Kroes et al., 2014). 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. In this study, 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 whether the clinical response to ECT response is associated with changes in neurobiological biomarkers using neuroimaging scans and blood samples obtained from the venous catheter, and whether these biomarkers at baseline can predict treatment response.

Onderzoeksopzet

Pre-treatment baseline measures are obtained before start of ECT. During treatment, HAM-D scores are obtained at least every 6 sessions to follow treatment response. Within one week after the last ECT session (and before the transition of possible maintenance ECT (<1 session per week)), all parameters are assessed again as post-treatment measurement. Thereafter, patients are evaluated at 2-week intervals the first 8 weeks, and at 4-week intervals for the remaining 12 weeks to determine possible treatment relapse.

Onderzoeksproduct en/of interventie

The subjects will be randomised to schema-ECT or control-ECT. ECT is conducted as usual according to national guidelines in both patient groups (Nederlandse Vereniging voor Psychiatrie, 2010). In the schema group, ECT is preceded by a structured interview using the arrow-down technique, a technique known from cognitive-behavioral therapy (CBT) to reactivate negative schemas. In the control condition, patients will be interviewed about details that are also of clinical relevance but are not expected to activate depressive schemas.

Contactpersonen

Publiek

Department of Psychiatry
Academic Medical Center
University of Amsterdam
PO Box 22660
G. Wingen, van
Amsterdam 1100 DD
The Netherlands
+31-(0)20-8913523

Wetenschappelijk

Department of Psychiatry
Academic Medical Center
University of Amsterdam
PO Box 22660
G. Wingen, van
Amsterdam 1100 DD
The Netherlands
+31-(0)20-8913523

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Diagnosis of major depressive disorder (MDD) without psychotic symptoms assessed with

the Mini Neuropsychiatric Interview (MINI)
• Clinical indication for ECT
• 18-70 years of age
• Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Bipolar disorder, schizophrenia, primary alcohol or drug abuse, or any cognitive disorder as assessed with the Mini Neuropsychiatric Interview (MINI)
• Patients with MR contraindications such as metal implants or claustrophobia will be excluded from the neuroimaging study

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	17-02-2014
Aantal proefpersonen:	98
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-02-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41362
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4289
NTR-old	NTR4433
CCMO	NL47246.018.13
OMON	NL-OMON41362

Resultaten