DELTA-neuroimaging.

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Relative to controls, remitted depressed patients have: 1. Increased negative attentional biases; 2. Decreased functional and effective connectivity between emotion-regulation networks; 3. Increased activations of the cognitive control system...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27041

Bron
Nationaal Trial Register

Verkorte titel
DELTA-neuroimaging

Aandoening

Major Depressive Disorder

Ondersteuning

Primaire sponsor: Academic Medical Center, AMsterdam
Overige ondersteuning: Dutch Brain Foundation (Hersenstichting)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Prospective Recurrence of MDD during 2.5 years of follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND:

Major depressive disorder (MDD) is a highly prevalent and disabling disease, especially because its symptoms tend to return. In general antidepressants reduce the risk of recurrence 2-fold, but after cessation this risk appears to increase again. For prediction of recurrence, the number of previous episodes is amongst the strongest predictors, together with residual symptoms, daily hassles and coping style. Recurrence of MDD has been considered from neuropsychological, brain network dysfunction, neurochemical and psychoneuroendocrine perspectives which have not yet been integrated.
Therefore, despite these perspectives of neurobiological substrates for recurrent depression, the underlying mechanisms of recurrence remain poorly understood, which will be improved by a multimodal approach in which neuroimaging will be combined with neuropsychological and neurobiological/neuroendocrine measurements in patients with recurrent depression.

AIMS:

With this research-protocol we aim to investigate six important issues regarding recurrences of MDD-episodes:

1. The differences between healthy controls and patients with recurrent MDD-episodes with respect to structural (sMRI) and functional (fMRI)-scans;

2. The differences in changes in resting state activations and HPA-axis activity after mood-induction between remitted MDD-patients and controls;

3. The differences in the relations between HPA-axis functioning, fatty acid status and neuroimaging findings between remitted MDD-patients and controls;

4. The predictive value of sMRI/fMRI, changes in resting state activations and HPA-axis activity after mood-induction, fatty acid status and their interactions for the occurrence of new relapse/recurrences;

5. The association between sMRI/fMRI, changes in resting state activations and HPA-axis activity after mood-induction and fatty acid status with the number of previous episodes;

6. What changes occur in brain functions, psychoneuroendocrinological measures and their interaction when patients have a recurrence of their depression;

7. What are the associations of the above neuropsychological, neuroendocrine and fMRI measurements with stress and reward in daily life?

DESIGN:

Prospective and retrospective cohort design, with a healthy control comparison group, and an age and sex matched controlled repeated measurements design in case of future (non-) recurrence in the next 2.5 years.

METHODS:

Patients and controls: Fifty remitted unipolar MDD-patients (35-65 yr, both sexes) with ¡Ý2 MDD episodes, without psychopharmacologic drugs for at least 4 weeks and fifty controls (age, sex and intelligence matched) will be recruited.

Measurements: Two phases (study entry and after recurrence of depressive symptoms) are studied. In Phase I, two blocks of psychological tests will be obtained, followed structural and functional magnetic resonance imaging (MRI). During the scanning, a mood induction will be performed. In Phase II, when patients experience a recurrence during follow-up, we will invite them for new psychological testing and an MRI-scan. At approximately the same moment during follow-up we will invite a matched patient (matched by age ¡À10 years and sex) who has not experienced a recurrence by then, for repeated testing as well.
Neuropsychological tests obtained are the Exogenous cueing task, Face recognition task, Emotional categorization task, Emotional Memory and the Internal Shift Task (both Phases) and the Dutch Adult Reading Test (Phase I only).
MRI scanning will consist of a structural scan, resting state scan, Reinforcement learning task, Magnetic resonance spectroscopy, Diffusion Tensor Imaging, Emotional faces and Cued Emotional Conflict Task (both Phases); in Phase I an Emotion regulation task and a repeated resting-state scan after a sad mood induction will be made.
Neurobiological/Neuroendocrine tests consist of blood collection for polyunsaturated fatty acids and brain derived neurotrophic factor, analysis of genetic polymorphisms and salivary cortisol measurements
Repeated momentary daily assessments will be obtained during 6 days at 10 random timepoints by applying the Experience Sampling Method.

Doel van het onderzoek

Relative to controls, remitted depressed patients have:

1. Increased negative attentional biases;

2. Decreased functional and effective connectivity between emotion-regulation networks;

3. Increased activations of the cognitive control system when regulating emotions in response to emotionally valenced pictures;

4. Blunted reward-signals in the ventral striatum, and increased activations of dopaminergic neurons in the VTA;

5. Increased glutamate and decreased glutamine/GABA signals in the pgACC and basal ganglia;

6. Increased cortisol and DHEAS levels after mood-induction.

Furthermore we expect that:

1. sMRI/fMRI or change in activations of resting state brain networks after mood-induction are predictive for recurrence (after prospective follow-up of 2.5 years);

2. Changes in cortisol and DHEAS levels after mood-induction predictive for recurrence (after prospective follow-up of 2.5 years);

3. Measures of stress and reward-sensitivity predict future recurrences (after prospective follow-up of 2.5 years);

4. Measures of stress and reward-sensitivity correlate with emotional biases, with reward/aversive learning and specific abnormalities in resting-state brain networks.

Onderzoeksopzet

1. Baseline;

2. Prospective follow-up every 4 months;

3. Retrospective follow-up for app. 10 years in subjects who participated in a previous study (DELTA).

Onderzoeksproduct en/of interventie

Apart from mood-induction during assessment no interventions applied.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

PATIENTS:

1. Age 35-65 yr;

2. Both sexes;

3. ≥2 MDD episodes according to a structured interview for DSM-IV (SCID);

4. In stable remission defined as a Hamilton depression rating scale (HDRS) ≤7 and Inventory for depressive symptomatology (IDS-SR) ≤14 for at least 10 weeks.

CONTROLS:

1. Matched for age, sex and years of education;

2. IDS-SR ≤14.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

PATIENTS:

1. Current diagnosis of alcohol or drug dependence, psychotic or bipolar disorder, predominant anxiety disorder;

2. Standard fMRI exclusion criteria (claustrophobia, implanted metal objects in the bodies);

3. Electroconvulsive therapy within two months before scanning;

4. A history of head trauma or neurological disease, severe general physical illness.

CONTROLS:

1. Personal (assessed by SCID) or 1st degree relative with psychiatric disorder;

2. Current diagnosis of alcohol or drug dependence;

3. Standard fMRI exclusion criteria (claustrophobia, implanted metal objects in the bodies);

4. A history of head trauma or neurological disease, severe general physical illness.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2011
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-12-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3609
NTR-old	NTR3768
Ander register	METC AMC : 11/050
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A