Neurocognitive mechanisms of relapse prevention in depression, a fMRI-study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26793

Source
Nationaal Trial Register

Brief title
NEW-PRIDE

Health condition

Depression, Prevention,Relapse, fMRI
Depressie, preventie, terugval, fMRI

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: NWO VENI grant 016.156.077; Hersenstichting Nederland (HS), Fellowship F2014(1)-21

Intervention

Outcome measures

Primary outcome

Testing whether preventive cognitive therapy in remitted patients results in increased prefrontal control and whether this increased prefrontal control results in a decrease in attentional biases and increase in emotion regulation capacity.

Secondary outcome

Predict individual treatment succes in remitted depressed patients based on neurocognitive measures.
Translate neurocognitive principles to clinically usefull measures to predict and monitor individual preventive cognitive therapy success.

Study description

Background summary

Major depressive disorder (MDD) is the most prevalent psychiatric disorder, characterized by at least one life disrupting depressive episode and high risk for relapse after recovery (40% within 2 years). Risk for relapse and chronic-MDD increases dramatically with the number of previous episodes. Therefore, preventing relapse in the remitted phase is a major, but largely overlooked opportunity in treating MDD. Preventive cognitive therapy (CT), a psychological therapy aiming at improving emotion regulation skills, in remitted-MDD has been successful in lowering relapse-risk, though not in all patients. Mechanisms underlying preventive-CT are unclear, hindering clinicians in predicting for whom preventive-CT is warranted. Reliable predictors of preventive-treatment success are currently lacking, yet urgently needed. Clearly, accurate prediction of preventive-success contributes to effective preventive-treatment allocation and lower relapse-rates. In this research, we hypothesize that the capacity of the brain’s prefrontal cortex to regulate emotional information is crucial for understanding and predicting preventive-CT-success. The main objective of this study is to understand the neurocognitive mechanisms of preventive-CT by studying neurophysiological (i.e. brain responsivity as measured with functional Magnetic Resonance Imaging and autonomic nervous system reactivity as measured from pupil dilation) and cognitive processes associated with attentional processing and regulation of emotional information. Secondarily, this study aims to identify neurophysiological and neurocognitive predictors of individual preventive-CT success. As routinely performing neuroimaging investigations for predicting treatment-success is clinically not feasible, a third aim of this study is to validate the pupil dilation-response (an autonomic index previously linked to emotion regulation-success and associated brain activation) as reflector of brain-activation during emotion regulation in remitted-MDD, for use in innovative non-imaging, brain-informed prediction and monitoring of preventive-CT success.

Study objective

We hypothesize that the capacity of the brain’s prefrontal cortex to regulate emotional information is crucial for understanding and predicting preventive-CT-success.

Study design

Screening: with the SCID-I, the IDS-SR , the DART

First phase: Questionnaires, computer tasks, fMRI-scan

Second phase: Preventive cognitive therapy (8x 45 mins)

Third phase: 3 months after 1st phase, similar as 1st phase.

Fourth phase: questionnaires, 1,5 year after 1st phase,

Intervention

Protocolised Preventive Cognitive Therapy

Contacts

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Eligibility criteria

Inclusion criteria

between 18 - 60 years of age

current remission (>2 months; according to criteria in DSM IV)

>2 major depressive episodesin past 5 years

recency of last episode < 2years

currently not using any anti-depressant medication (>4 weeks)

Exclusion criteria

current major depressive episode

current use of anti-depressant medication

neurological problems

drug abuse

use of psychotropic medication other than frequent use of benzodiazepine
anu other current DSM IV Axis-I diagnosis, as objectified with the SCID-I

MRI contra indications

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2015
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-08-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47768
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5219
NTR-old	NTR5368
CCMO	NL53205.042.15
OMON	NL-OMON47768

Study results