Brain imaging in Posttraumatic Stress Disorder (PTSD): effects of paroxetine and Trauma-Focused Cognitive Behavioural Therapy (TF-CBT)

Published: 24-11-2009
Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders
Study type	Observational invasive

Summary

ID

NL-OMON33322

Source
ToetsingOnline

Brief title
Brain imaging in PTSD, effects after treatment

Condition

- Psychiatric disorders

Synonym
PTSD en stress disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ONWA

Intervention

Keyword: fMRI, paroxetine, PTSD, TF-CBT

Outcome measures

Primary outcome

Main study parameter included is the difference in structural and functional imaging results in patients with PTSD versus controls. Secondly, effective versus non-effective therapy (TF-CBT and paroxetine) will be compared with regard to structural and functional differences. Furthermore, neuro-immune, neuro-endocrine and neurocognitive data will be associated with structural and functional differences in patients and controls. Functional differences in the small subgroup of PTSD-patients receiving biofeedback as an adjunct to TF-CBT will be compared to PTSD-patients receiving regular TF-CBT as part of the main treatment study.

Secondary outcome

na

Study description

Background summary

In patients with post traumatic stress disorder (PTSD) several structural as well as functional brain abnormalities and dysfunctions have been found, such as in the temporal structures (i.e,. the limbic system including amygdala and hippocampus) and the prefrontal cortical brain regions. Regarding structural changes in the brain of PTSD patients, the most salient finding is that hippocampal volumes are smaller in patients with PTSD. Concerning alterations in brain activation, as measured with functional neuroimaging, it has been found that trauma-related memories in PTSD cause hyperactivation of the

temporal brain regions like the amygdale and insula. In addition, data suggests a reciprocal relation between the function of the medial prefrontal cortex and amygdalae function in PTSD and that responses to fear and stress in PTSD patients are not sufficiently suppressed by the medial prefrontal cortex. It is, however, unclear whether these disturbances are pre-existent risk factors or occurring after trauma and/or alongside PTSD. Moreover, there is yet little evidence for the influence of effective treatment on functional differences.
The proposed study is part of our main study *The effectiveness of Paroxetine versus Trauma-Focused Cognitive Behavioural Therapy in the treatment of Posttraumatic Stress Disorder (PTSS)* (MEC 09/080 # 09.17.0843as).

Study objective

Our main objective is to assess whether structural and functional differences in the brain can be demonstrated between PTSD patients and controls during performance of an emotionally evoked task, in resting state and during a working memory task. Secondly, we aim to assess whether any structural and functional differences will be apparent following effective treatment and whether functional differences will be found between two different treatments, i.e., trauma-focused cognitive behavioural therapy (TF-CBT) and the Selective Serotonine Reuptake Inhibitor (SSRI) paroxetine. Furthermore, the association of neuro-immune, neuro-endocrine and neurocognitive data with structural and functional data will be explored as well as white matter integrity.

Study design

We propose to conduct an fMRI study comparing patients with chronic PTSD (N=48) [taking part in the main study randomized to pharmacological treatment with paroxetine (N=20) or to psychotherapy (TF-CBT) (N=20) or taking part in a pilot study of breathing biofeedback as an adjunct to TF-CBT (N=8)] with trauma exposed controls (N=20) and healthy controls (N=20). All participants will be examined using (functional) Magnetic Resonance Imaging ((f)MRI). PTSD patients (N = 48) will be scanned prior to treatment, immediately after treatment and 12 months later and data from assessments already performed in the main study and biofeedback pilot study, respectively, will be linked to the current fMRI substudy. Controls (N=40) will have a single scanning moment and additional neuropsychological, neuro-immune and neuro-endocriene data will be collected only once for these controls.
Patients suffering from chronic PTSD who are randomly assigned to either 8-12 weekly sessions of TF-CBT (N = 20) or 24-weeks of flexible-dose open treatment (20 mg to a maximum of 60 mg) with paroxetine (N = 20) or to TF-CBT with an adjunct of biofeedback training (N=8) will be scanned prior to treatment and 1 week after treatment. PTSD-patients (N=40) taking part in the main treatment study will also be assessed on the long term, i.e., 12 months after respective treatments are finished. Measurements will include (f)MRI and DTI. The control groups will be assessed at one single time-point. All participants will perform

two tasks, one emotionally evoked task and one working memory task. In addition, participants will be scanned during resting state.

Study burden and risks

The burden and risks associated with participation in this study is reasonable. The participants who are receiving either trauma focused behavioural therapy (TF-CBT) or treatment with paroxetine, both considered to be the effective treatments for PTSD, will for this study be exposed to the (f)MRI before and immediately after treatment. This may be considered a burden, but no risks in terms of adverse events or treatment outcome are related with this procedure. Participants will receive an additional compensation for participating in the study.

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

CAPS score of * 50 (only for PTSD patients)
Male and female, aged 18 years and above
Written informed consent
Eligible for exposure therapy
Eligible for fMRI (no metals, pacemaker or claustrophobia)

Exclusion criteria

Suicidal risk
Presence of any of the following DSM IV diagnoses, at present or in the past: psychotic disorder incl. schizophrenia, a bipolar disorder, depression with psychotic features, a panic disorder with or without agoraphobia or excessive substance related disorder over the past 6 months
Primary diagnosis of severe depressive disorder
Presence of primary or co-morbid personality disorder
An organic disorder
Taking any psychotropic medications at present

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2009
Enrollment:	88
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL29288.018.09