Neural correlates of trauma-focused psychotherapy in PTSD: A longitudinal fMRI investigation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON48147

Source
ToetsingOnline

Brief title
Neural correlates of PTSD

Condition

- Other condition
- Dissociative disorders

Synonym
psychological trauma, PTSD

Health condition

Post-traumatic stress disorder

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: neural correlates, PTSD, treatment predictors

Outcome measures

Primary outcome

The main study parameters are differences in BOLD activation patterns between responders vs. non-responders following the fMRI paradigms. A treatment responder analysis will be conducted to identify (1) pre-post changes in brain activation responding to a script-driven trauma confrontation protocol and emotion reactivity task and (2) pre-therapy activation which could predict treatment outcome. Functional imaging data will be analyzed with region-of-interest and whole-brain exploratory analysis.

Secondary outcome

Secondary parameters include 1) the psychophysiological reactivity elicited during the functional imaging paradigms (script driven imagery and emotion reactivity), 2) resting-state functional imaging data for connectivity analyses, and 3) patient characteristics to describe the patients and characterize possible subgroups of patients (those who will and those who will not benefit from treatment).

Study description

Background summary

Post-traumatic stress disorder (PTSD) is a debilitating condition in which patients suffer from intrusions, avoidance, and hyperarousal following a traumatic event. Trauma-focused psychotherapies (TFT), including exposure and re-processing of the traumatic memories, are most effective in reducing PTSD symptomatology. Approximately one third of PTSD patients do not depict noteworthy improvements following treatment, and no reliable predictors for treatment outcome have been identified yet. A promising path towards finding objective treatment predictors is to understand brain-based characteristics and the neural underpinnings of PTSD symptomatology. Neurobiological models suggest that PTSD symptoms correspond with dysfunctional fronto-limbic neural circuitry and that psychotherapy strengthens top-down modulation of hyperactive limbic regions. Meanwhile, it has been hypothesized that PTSD patients with elevated dissociation levels do not respond equally well to treatment as dissociation is expected to interfere with habituation during exposure and negatively affects lower brain regions regulating physical reactions. Only few neuroimaging pre-post treatment studies in PTSD have provided empirical evidence for the proposed models. There is a strong necessity for well-powered neuroimaging research to identify treatment-related changes in brain function and neural predictors of who will and will not profit from trauma-focused therapy.

Study objective

The current study*s primary aim is to test how trauma-focused therapy affects PTSD symptom-specific neural activity, and investigate neural markers that may predict treatment response to trauma-focused exposure. Furthermore, it is expected that assessment of psychophysiological reactivity and functional connectivity between regions of interest can elucidate other potential markers of psychotherapeutic gains in PTSD.

Study design

The current study employs an observational pre-post therapy design in which symptom-related brain activation of 60 PTSD patients enrolled in trauma-focused therapy will be assessed before and after the trauma-processing phase. During functional neuroimaging, participants will undergo two experimental tasks. The first task is script-driven imagery, in which participants attentively listen to an audiotaped narrative of a personal a) traumatic and b) neutral event in a blocked design. The second task is an emotion reactivity task to assess neural correlates of conscious and non-conscious processing of fearful (vs. neutral) faces.

Study burden and risks

Participation consists of 4 sessions (total duration: 7 hours); Participants undergo a neuroimaging session (duration: 90 min) and a clinical assessment session (duration: 60-120 minutes) once before and after therapy. The first

clinical assessment session comprises a clinical interview (45-60 minutes), script collection (30 minutes), and filling out a questionnaire booklet (60 minutes). In the neuroimaging sessions, participants answer several questionnaires (30 minutes), and then undergo fMRI scanning (45 minutes) including two tasks (script-driven imagery and emotional reactivity). During scanning, the participants* psychophysiological data (heart rate, skin conductance reactivity, and respiration) will be recorded. The second clinical assessment session entails an interview to assess PTSD severity post-treatment (45-60 minutes). While acknowledging the participation burden and potential distress related to the study procedures, all techniques have been extensively tested in traumatized patient groups and trauma-focused research participation has presented minimal risk to its subjects. Concerning the fMRI scanner, participants will be exposed to a field strength of 3 Tesla and scanner noise. Thus far, there is no evidence to suggest that exposing humans to a magnetic field of this strength has a negative influence on health. With regard to the noise, earplugs will be provided. To minimize the risk of claustrophobic sensations in the scanner, patients will be screened for a history of claustrophobia and will be offered to lay in a mock scanner to estimate their comfort level inside a MR scanner. No disadvantages of the heart rate measures and skin conductance measures are known or expected. The study is not intended to benefit the participants directly, but they will receive a compensation of ¤ 70,- for their participation.

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

1. Participants must be full of age (18 years or older).
2. Meet the criteria for post-traumatic stress disorder (PTSD).
3. Must be enrolled in trauma-focused psychotherapy (TFT).
4. Participants must be capable of giving consent.

Exclusion criteria

1. Presence of metallic devices, e.g. metal implants or cardiac pacemaker
2. Meet diagnostic criteria for
a. Pain disorder
b. Bipolar disorder
c. Dissociative Identity Disorder
d. Schizophrenia
e. Neurological disorders
3. Alcohol or drug abuse in the last 6 months
4. Suspected pregnancy
5. Claustrophobia
6. Refusal that general practitioner will be informed when structural brain abnormalities could be detected during experiment

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2020
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	30-10-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL70837.042.19