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Stress, habits and attachment in obsessive-compulsive disorder (SHA-OCD)

Submission date
14/02/2019

Recruitment status
No longer recruiting

Registration date
21/02/2019

Overall study status
Completed

Last Edited
27/03/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Obsessive-compulsive disorder is a debilitating psychiatric disorder. For example, patients suffer from obsessive cleanliness and washing tendencies. Aim of this study is to get to understand better what make patients vulnerable to develop or worsen compulsive symptoms. This kind of knowledge is important to eventually improve treatment options. Prior research shows a relationship between stress and complaints of OCD. In this study we want to find out more precisely how this relationship works, by investigating behavioral and brain responses.

Who can participate?
In this study we will compare results of participants with OCD with healthy volunteers (without a psychiatric disorder current or in the past). Participants of both gender and between 18 and 65 years of age could participate. Healthy volunteers are recruited so that they have on average the same age and gender distribution as the participants with OCD.

What does the study involve?
We will carry out this study by making participants with OCD and healthy control participants mildly stressed and directly afterwards measuring their brain activity during specific computer tasks (a kind of puzzles), of which we know that patients with OCD do usually perform them differently than people without OCD.
Besides that, we will show different pictures with OCD related images, general fearful images and neutral images. During the viewing of these pictures, we measure brain responses of participants and let them report how they feel. To provoke stress, participants are asked to keep their hand for three minutes in ice-cold water. What participants do not know (but what is explained on the same day, directly after all tests are completed) is that the research assistant that carries out the stress procedure is acting distantly. This procedure has been tested and appeared stressful in prior research. All participants are examined twice, once after stress provocation and once in a control condition. On both days tests are identical, except that in the neutral condition there is no stress provocation. Furthermore, we want to investigate if differences in experiences of social support is related to the development of complaints of compulsivity. We will investigate this by measuring in the same group of participants their

experience in close relationships and interviewing them about their memories of their relationships with parents or primary caretakers in their youth. Then, we will look if these outcomes are related to the effect of stress on the brain.

What are the possible benefits and risks of participating?
There is no individual benefit from participating in this study. Functional MRI is painless and without risk. The stress provoking procedure and laying in a MRI scanner might be experienced unpleasant.

Where is the study run from?
The study is run from the Academic Medical Center in Amsterdam. Test days are performed in the Spinoza Centre for Neuroimaging in Amsterdam.

When is the study starting and how long is it expected to run for?
The study has started in April 2013 and will be completed in July 2020. All data from the tests are gathered between 2016 and 2018.

Who is funding the study?
Zon MW (the Hague, the Netherlands)

Who is the main contact?
Wieke van Leeuwen, w.a.leeuwenvan@amc.uva.nl

Contact information

Type(s)
Public

Contact name
Ms Wieke van Leeuwen

Contact details
Meibergdreef
Amsterdam
Netherlands
PO Box 22660, 1100 DD
0031-208913600
w.a.leeuwenvan@amc.uva.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

NL49200.018.14 in Dutch CCMO register

Study information

Scientific Title
Behavioural and neuroimaging effects of stress, habits and attachment in obsessive-compulsive disorder (SHA-OCD)

Acronym
SHA-OCD

Study objectives
In patients with OCD, stress facilitates a shift from goal-directed to habitual behaviour and heightened amygdala response to biologically salient stimuli, accompanied by changes in resting state network activity and white matter integrity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/08/2014, Medical Ethics Committee of Amsterdam UMC, location AMC (Meibergdreef 9 1105 AZ Amsterdam; +31 205667389; mecamc@amc.uva.nl), ref: 2014_168#B2014742
Amendment approved: 24/02/2017; reference: 2014_168#B2017104

Study design
fMRI study with a counterbalanced cross-over design

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Obsessive-compulsive disorder

Interventions
Participants will undergo three study visits on different days. On day 1 (total duration of 120 minutes) informed consent is signed and participants will undergo psychiatric diagnostic

interviews / questionnaires and the Adult attachment Interview. On day 2 and 3 (with 1 week in between), participants undergo MRI scanning. Total scanning time will be approximately 60 minutes, consisting of the habit task, the picture viewing task, the emotional face matching task, resting-state fMRI, DTI and structural MRI. A stress induction procedure (or neutral control condition) of approximately 10 minutes will be performed directly prior to MRI scanning. During the stress procedure participants will be subjected to the socially evaluated cold-pressor test (SECPT). It has been extensively researched and widely used. In the stress condition, participants immerse their right hand up to and including the wrist for 3 minutes (or until they could no longer tolerate it) into ice water (0-4°C), just prior to scanning. During hand immersion, participants are monitored by an unfamiliar person and videotaped. They are informed that these recordings will be analyzed for facial expressions. During the control condition, participants submerge their right hand for 3 minutes in warm water (35-37°C). They are neither monitored nor videotaped.

Intervention Type
Behavioural

Primary outcome measure
1. Whether stress facilitates a shift from goal-directed to habitual behaviour measured using behavioral data from a two-step sequential choice task that differentiates between model-free (habitual) and model-based (goal-directed) behavioral strategies.
2. Subjective anxiety ratings on a self-rating scale in response to visual OCD-related, general fearful and neutral stimuli.
3. Brain activity during at rest and during tasks measured using fMRI voxel-based signal covariation with task parameters.

Secondary outcome measures
1. Whether stress results in heightened amygdala response to biologically salient stimuli fMRI voxel-based signal covariation with task parameters.
2. How stress affects the functional integrity of the goal-directed and habit networks measured using a seed-to-voxel analysis.
3. Structural integrity of the implicated neural networks as measured with DTI tractography
4. Individual attachment style measured with the Adult Attachment Interview (semi-structured interview) and Experiences in Close Relationships scale (self-report scale)

Overall study start date
01/04/2013

Completion date
11/10/2018

Eligibility

Key inclusion criteria
Patients:
1. Diagnosis of OCD with obsessions and compulsions assessed with the MINI Neuropsychiatric Interview (MINI)
2. Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) score cut-off of 12
3. 18-65 years of age
4. Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements

Controls:
1. 18-65 years of age
2. Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
31 participants with OCD and 31 matched healthy control participants

Total final enrolment
46

Key exclusion criteria
Patients:
1. Current major depressive disorder, bipolar disorder, psychotic disorder, alcohol or substance dependence, or any cognitive disorder as assessed with the MINI
2. Major head trauma or neurological disease, current or in history
3. MRI contraindications such as metal implants, claustrophobia, left-handedness, pregnancy
4. Self-reported inability or unease to cease smoking for 3 hours prior to testing
5. Endocrinological disorders or regular use of corticosteroids
6. Current treatment with antipsychotic medication
7. Use of other psychotropic medication (apart from SSRI's or tricyclic antidepressant), or of recreational drugs over a period of 72 hours prior to each test session, and use of alcohol within the last 24 hours before each measurement
8. Irregular sleep/wake rhythm (e.g., regular nightshifts or cross timeline travel).

Controls:
1. Current or past psychiatric diagnosis as assessed with the MINI
2. Major head trauma or neurological disease, current or in history
3. MRI contraindications such as metal implants, claustrophobia, pregnancy
4. Self-reported inability or unease to cease smoking for 24 hours prior to testing
5. Endocrinological disorders or regular use of corticosteroids
6. Use of psychotropic medication, or of recreational drugs over a period of 72 hours prior to each test session, and use of alcohol within the last 24 hours before each measurement
7. Irregular sleep/wake rhythm (e.g., regular nightshifts or cross timeline travel).

Date of first enrolment
19/01/2016

Date of final enrolment
01/07/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Study participating centre
Spinoza Neuroimaging Centre
Meibergdreef 75
Amsterdam
Netherlands
1105 BK

Sponsor information

Organisation
Zon MW

Sponsor details
PO Box 93245
The Hague
Netherlands
2509 AE
031-70-3495111
info@zonmw.nl

Sponsor type
Not defined

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Government

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/07/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/02/2020	27/03/2023	Yes	No