

# Confidence in context in obsessive-compulsive disorder.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Psychiatric and behavioural symptoms NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON49752

### Source

ToetsingOnline

### Brief title

Confidence in context

### Condition

- Psychiatric and behavioural symptoms NEC

### Synonym

compulsive disorder, obsessive compulsive disorder

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** NWO Veni

## Intervention

**Keyword:** confidence, obsessive-compulsive disorder

## Outcome measures

### Primary outcome

There are four main study parameters:

- 1) The difference in confidence levels in symptom-related context versus neutral context.
- 2) The coupling between confidence and learning within a volatile environment.
- 3) Metacognitive monitoring: the influence of post-decisional evidence on confidence level updating (i.e. changes of mind).
- 4) Global self-confidence and the relationship to local confidence levels.

### Secondary outcome

Symptom severity

## Study description

### Background summary

Obsessive-compulsive disorder is a psychiatric condition associated with repetitive and functionally impairing actions (i.e. compulsions, such as checking behaviors), mostly performed to alleviate distress induced by intrusive thoughts (i.e. obsessions). Patients suffering from this disorder compulsively engage in behavior and pathological decision-making that leads to serious life impairments and suffering. It is important to study the underlying behavioral processes that go together with this disorder.

With every decision we make, a feeling of confidence about that choice arises, which is crucial for learning and guiding our future decision-making behavior. Confidence is being defined as the subjective feeling of being accurate about a choice or decision, and is a metacognitive construct. Studies have shown that confidence mostly accurately maps onto performance in various tasks. Importantly, however, abnormal confidence judgments that do not reflect reality

(i.e. one's subjective feeling of being correct does not match with one's actual performance) may play a crucial role in pathological decision-making typically seen in psychiatric disorders. Indeed, in a recent review we found evidence for confidence abnormalities across a wide range of psychiatric disorders, showing strong evidence for a decline in confidence in (sub)clinical OCD. Multiple studies have shown a decline in confidence both in situations where patients engage in typical OCD behavior, are in a neutral situations or in a OCD-relevant context. Lastly, this review revealed a robust association between confidence abnormalities and the severity of psychiatric symptom.

In the current study we want to further explore confidence dysfunctionality in OCD subjects by studying confidence in various contexts and as a more global construct:

Confidence is not a unitary construct, since confidence abnormalities are differently expressed in various contexts. Therefore, the role of context in confidence abnormalities should be further delineated. For example, it is possible that confidence abnormalities differ in strength when patients are in a context related to their symptoms. Moreover, in the real world, we have to adapt to inconsistent feedback and a volatile, ever-changing, environment and OCD patients have shown difficulties with adapting to these types of situations. Learning under these unstable conditions is thought to be more reliant on well calibrated confidence judgments. Therefore, in this study, we want to explore the relationship between learning behavior and confidence levels in a volatile environment. Furthermore, we want to investigate whether OCD patients show irregularities in using their confidence judgments for regulating their behavior (i.e. metacognitive control). Lastly, global beliefs about our competence have a role in our higher-order behavioral control, as they influence our motivation and goals. Distortions in global self-belief have been related with various psychiatric disorders. However, in OCD there is no knowledge on the mechanisms that form global confidence levels and how they relate to local confidence levels in situations with and without immediate feedback.

## **Study objective**

Our objective is to study confidence abnormalities in OCD. We want to study:

- 1) Confidence abnormalities in a symptom-related versus a neutral context,
- 2) Learning-confidence coupling in a volatile environment in OCD,
- 3) Metacognitive monitoring (i.e. using confidence for behavioral regulation) via changes of mind in OCD,
- 4) Global self-confidence and its relationship to local confidence judgments in OCD.

## **Study design**

To investigate our main objectives we will use a cross-sectional study design testing behavioral outcome measures using various computerized tasks in 30 OCD patients and 30 healthy control (HC) subjects. The inclusion of a healthy control group is critical to relate observed behavioral outcome measures in the patient group with a group without psychiatric disorders. These groups will be matched on age, sex and educational level and compared to each other. All groups will undergo the same behavioral cognitive paradigms. These outcome measures will be compared within the groups (i.e. related to symptom severity) and between groups.

The duration of the study is 4 hours per participant: the computer tasks will have a total duration of 2.5 hours and assessing questionnaires will have a total duration of 1.5 hour.

### **Study burden and risks**

The burden of the study entails a single visit of 4 hours of time participation, in which the participants perform computer tasks and fill in questionnaires. This study entails no risks and no physical discomfort. There will be no direct clinical benefit for the participants of this study, however, this study is expected to result in increased insight in the behavioral mechanisms of confidence abnormalities in OCD, which will contribute to the development of treatment alternatives, allowing for personalized therapies focusing on individual deficits in disorder-specific context.

## **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

Inclusion process: Potential participants are informed about the study and will receive an information letter. After this, they are contacted by telephone. If interested to participate, screening for inclusion and exclusion criteria is performed. In order to be eligible to participate in this study, a subject must meet all of the following criteria:

OCD subject:

- DSM-5 diagnosis of OCD
- No other psychiatric disorder
- Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) score cut-off of 12
- 18-65 years of age
- Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements

HC subject:

- No current psychiatric diagnosis or history of OCD.
- 18-65 years of age
- Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirement

### Exclusion criteria

All groups:

- Current major depressive disorder, bipolar disorder, psychotic disorder, alcohol or substance dependence, or any cognitive disorder as assessed with the MINI neurological disorders section
- IQ below 80
- Insufficient command of the Dutch language
- recent (<2 weeks) use of psychotropic medication other than naltrexone (smoking and nicotine dependence is allowed in all groups).

- Endocrinological disorders or regular use of corticosteroids
- Current treatment with SSRIs, tricyclic antidepressant or antipsychotic medication
- Use of other psychotropic medication or recent use 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.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2021
Enrollment:	60
Type:	Actual

## Ethics review

Approved WMO	
Date:	06-03-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	03-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO  
Date: 06-04-2021  
Application type: Amendment  
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	NL71836.018.19