Interoceptive fear conditioning and generalization to respiratory sensations in panic disorder patients and healthy controls

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Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON39913

Source
ToetsingOnline

Brief title
Interoceptive fear and generalization

Condition

- Anxiety disorders and symptoms

Synonym
anxiety disorder, panic disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Generalization, Interoceptive fear, Panic disorder

Outcome measures

Primary outcome

Primary output will be the measures of fear learning to the CS including: the skin conductance response, a potentiated startle blink (EMG), respiration, electrocardiography and self-reported expectancy of the US. The questionnaires (e.g. ASI, PAS, FQ, CLQ, STAI, fear of suffocation) and autobiographical memory will be secondary output variables. A third output variable is the measurement of heart rate variability at rest, derived from a 10 min ECG prior to the experiment.

Secondary outcome

Not applicable

Study description

Background summary

Interoceptive processes may play an important role in the pathogenesis of panic and anxiety disorders, prominently through the principles of classical conditioning. However, despite their clinical importance, they are largely understudied. Further focus on interoceptive fear conditioning and generalization for interoceptive stimuli is important for the research of etiology and treatment of not only panic disorder but also other psychosomatic disorders and anxiety in general. If interoceptive conditioning and generalization indeed play an important role, a new perspective for future treatment is offered.

The overall objective of this study is the investigation of interoceptive fear

conditioning and generalization in both healthy subjects and a group of panic patients. For the conditioning procedure, we will make use of respiratory stimuli that are not aversive and completely harmless (conditioned stimulus, CS). As the aversive stimulus we use a short, inspiratory, occlusion (US). The duration of the occlusion is determined for each individual subject, based on how long they are able to hold their breath, after expiration. After the acquisition phase, subjects will show a slight fear response with respect to the CS that was coupled with the occlusion. During a subsequent generalization test, we can then examine to what extent participants show a fear response to other, similar, respiratory sensations. After completion of the generalization test, we ensure that all conditioned fear responses are extinguished by using an extinction procedure (CS-alone presentations). More specific, one of our expectations is a stronger fear acquisition and generalization in panic patients, compared to the healthy control group.

Study objective

The overall aim of this study is to investigate interoceptive conditioning of fear and it*s generalization in both panic/anxiety patients and healthy control subjects. Therefore we have three specific objectives.
The first objective is to replicate findings in healthy persons on how interoceptive fear can be learned in a novel paradigm (Pappens, Smets, Vansteenwegen, Van den Bergh, & Van Diest, 2012). In addition, we will investigate whether panic patients acquire such interoceptive fear more easily. In this paradigm, a slight sensation of obstructed breathing (created by a flow resistor, or, *load* of 20 $cmH^2O/l/s$) serves as the interoceptive conditioned stimulus (CS) whereas a short interruption of the airflow (occlusion) serves as the unconditioned stimulus (US). When the sensation created by the *load* becomes a predictor for the occlusion, participants will acquire fear to this originally benign sensation.
The second aim is to investigate to what extent this acquired fear generalizes to other, similar, sensations. Therefore we present different intensities of the obstructed breathing sensations (range 5 - 30 $cmH^2O/l/s$) to verify if participants also show fear responses to these stimuli (generalized stimulus, or GS*s) that were never presented before.
The third aim is to investigate individual difference variables in the extent of generalization and the course of panic disorder. Variables of interest include heart rate variability at rest, memory for specific learning events (as measured by the Autobiographical Memory Test (AMT) and the Rey Visual Learning Design Test (RVDLT).

Study design

The study involves a paired/unpaired design that will be run both in a group of persons with panic disorder and a healthy control group.
A resistive load (CS) will be used as a predictor for a short occlusion of the

airflow (US), in the acquisition phase, the paired group receives paired presentations of CS and US, whereas both stimuli are explicitly unpaired in the unpaired group. During generalization, both groups receive partially reinforced presentation of the original CS and unreinforced presentation of the other load-intensities (GS*s)

Study burden and risks

There are no risks associated with this study and both medical and personal information are treated according to privacy and confidentiality regulations.

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

Panic patients and healthy volunteers aged between 18-65 years and in a good physical condition

Exclusion criteria

• History of pulmonary disease (including asthma and lung fibrosis)
• History of cardiovascular disease (including cardiac failure, suspicion of infarct, cardiomyopathy, transient ischemic attack (TIA), angina pectoris, arrythmias)
• Hypertension (diastolic > 100; systolic > 170)
• Personal or familial history of cerebral aneurysm
• Pregnancy
• Epilepsy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-09-2013
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL41493.068.12