The role of fear learning in panic disorder.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20198

Source
Nationaal Trial Register

Brief title
interoceptive conditioning

Health condition

Panic Disorder
CO2 challenge
interoceptive stimuli
interoceptive conditioning

Sponsors and support

Primary sponsor: performer= University of Maastricht
Source(s) of monetary or material Support: Performer = University of Maastricht

Intervention

Outcome measures

Primary outcome

The subjective reports of the participants measured by the Visual Analogue Scale – Fear (VAS-F) during the test part.

Secondary outcome

The physiological responses of respiration rate, tidal volume and FetCO2 and the subjective report by Panic Symtom List (PSL) during the test part.

Study description

Background summary

More than 20% of the general population experience a panic attack once in their lives; however, only a minority goes on to develop panic disorder. The alarm theory tries to explain the etiology of panic disorder through interoceptive conditioning. To date studies concerning panic disorder and interoceptive conditioning are limited.

The aim of the present study is to establish intero-interoceptive fear conditioning in healthy participants in a differential conditioning paradigm. We want to make use of “real” interoceptive conditioned stimuli (CS): a low respiratory load and small infusions of pentagastrin will be used as CS. CO2-enriched air is used as unconditioned stimulus.

This study involves a double-blinded randomised design.Healthy volunteers with an age range between 18-65 years are included in the study. The main study outcome are the subjective reports (fear and physical symptoms) and the physiological measurements (respiration rate, tidal volume) that are assessed during the test-phase.

Study objective

We want to establish intero-interoceptive conditioning in healthy volunteers for the better understanding of the development of panic attacks into panic disorder.

Study design

All assesments are measured before and after each trial. The differences between the trial in the test part are important.

Intervention

We want to establish intero-interoceptive fear conditioning with a differential conditioning paradigm. We want to make use of “real” interoceptive conditioned stimuli (CS): A low respiratory load (1.43 kPa/l/s) resistance and small infusions of pentagastrin (0.2 µg/ kg) will be used as CS. CO2-enriched air is used as unconditioned stimulus (UCS). To rule out possible procedural effects also a placebo injection and placebo resistance is included in this study. The experiment consists of two parts, acquisition and test. During acquisition we want to establish conditioning (linking CS to the UCS). During the test part only the CS is given

without the UCS.

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Eligibility criteria

Inclusion criteria

1. Healthy volunteers aged between 18-65 years;

2. Good physical condition.

Exclusion criteria

1. History of pulmonary disease (including asthma and lung fibrosis);

2. A psychiatric disorder;

3. History of cardiovascular disease (including cardiac failure, suspicion of infarct, cardiomyopathy, TIA, angina pectoris, arrythmias);

4. Hypertension (diastolic > 100; systolic > 170);

5. Personal or familial history of cerebral aneurysm;

6. Pregnancy;

7. Epilepsy;

8. Psychotropic medication use;

9. Use of á2- or â-blockers;

10. Idiosyncratic response to pentagastrin;

11. If participants refuse insight in deviant findings.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-07-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-06-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34392
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2261
NTR-old	NTR2387
CCMO	NL32415.068.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34392

Study results

Summary results
N/A