Interoceptive fear conditioning by using interoceptive stimuli and CO2 enriched air in healthy participants.

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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: a low respiratory load and small...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON34392

Source
ToetsingOnline

Brief title
Interoceptive conditioning

Condition

- Anxiety disorders and symptoms

Synonym
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: CO2 inhalation, interoceptive condtioning, interoceptive stimuli, panic disorder

Outcome measures

Primary outcome

The main study outcome are the subjective reports of fear (VAS-F) during the

test-phase.

Secondary outcome

The secondary outcomes are the self reports of physical symptoms and the

physiological measurements (respiration rate, tidal volume) that are assessed

during the test-phase.

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.

Study objective

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: a low respiratory load and small infusions of pentagastrin. CO2-enriched air is used as unconditioned stimulus.

Study design

This study involves a double-blinded randomised design

Intervention

The use of pentagastrin/placebo or inspiratory load/placebo.

Study burden and risks

There are no risks associated with this study. During CO2-inhalation participants can feel symptoms of arousal and fear, but these are of short duration and are harmless. There are no long term effects of CO2-inhalation. There are also no risks associated with the injections or with the inspiratory loads. In our study we will only use a very small dosage of pentagastrin and inspiratory load, which will only causes feelings of discomfort/ resistance in healthy volunteers. Both will only be administrated to healthy volunteers. The burden for participants is rather low. Screening faze will take 30 minutes. The duration of the experiment is 45 minutes and there is a pause of 30 minutes. The experiment consists of two visit to the laboratory.

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

A good physical condition and age between 18-65 years

Exclusion criteria

A psychiatric disorder- history of pulmonary disease (including asthma and lung fibrosis)- history of cardiovascular disease (including cardiac failure, suspicion of infarct, cardiomyopathy, TIA, angina pectoris, arrythmias)- hypertension- personal or familial history of cerebral aneurysm- pregnancy- epilepsy- psychotropic medication use- use of α2- or β-blockers- idiosyncratic response to pentagastrin- 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:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-12-2010
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO

Date:	01-07-2010
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

ID: 20198
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL32415.068.10
Other	nog niet gekregen
OMON	NL-OMON20198