Ordors eliciting Fear: a learning model for Multiple Chemical Sensitivity

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32719

Source
ToetsingOnline

Brief title
Odors and Fear

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
Multiple Chemical Sensitivity or Idiopathic Environmental Intolerance

Health condition

Meervoudige Chemische Overgevoeligheid

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: NWO-VIDI

Intervention

Keyword: classical conditioning, fear, multiple chemical sensitivity, ofaction

Outcome measures

Primary outcome

The CS is the presentation of an odor with a duration of 6 seconds. The US is an electrical shock, delivered 500 ms to the fingers, presented directly following the CS+. Per condition, 25 participants will be tested (N = 50 in total). As dependent variable, the electrodermal response will be measured via electrodes attached to two fingers.

Secondary outcome

As a secundary physiological measures heart rate frequency as a second indicator of phsyiological arousal assessed via a clip on one finger of the hand, and sniffing behavior, via the assessment of air presssure differences through a cannula in the nose, will be investigated during each phase of the experiment. Evaluation of odor intensity and odor pleasantness will be completed after each odor presentation by means of Visual Analogue Scales (VAS), to investigate how odor evaluation develops during the expected classical conditioning process. Explicit expectation of the shock will be assessed by means of a VAS on expectation for both odors. Finally, questionnaires will be administered containing questions about demographics, general health, and neuroticism.

Study description

Background summary

Specific symptoms of Multiple Chemical Sensitivity (MCS), such as headache, dizziness and chest palpitations, may result from learning by classical fear conditioning. In classical conditioning, a neutral stimulus is paired with an unconditioned stimulus (US) that causes fear. The neutral stimulus may thereupon provoke fear as a conditioned stimulus (CS). In MCS sufferers, a representation of a fearful encounter (US) with an odor is activated when the odor (CS) is smelled again, which causes fear as a conditioned response (CR). Physiological changes resulting from fear might subsequently cause several symptoms typical for MCS.

Study objective

This study will investigate whether odors can be conditioned to fearful events and themselves elicit fear in humans. Fear conditioning will be tested on two odors: a pleasant odor and an unpleasant odor. The research questions are 1) can odors be conditioned to fear and elicit fear themselves, and 2) can unpleasant odors be conditioned to fear better than pleasant odors?

Study design

An experimental study will be conducted using a differential conditioning paradigm. This holds that both a target odor (CS+) and a control odor (CS-) will be presented, but only the target odor will be occasionally paired with an electrical shock (US). For fifty percent of the participants (randomized) the CS+ will be the pleasant odor and the CS- will be the unpleasant odor. For the other fifty percent the CS+ and CS- are swapped. A habituation phase will investigate baseline measures. This is followed by an acquisition phase, in which only the CS+, not the CS-, will be paired with shocks. In a test phase, physiological responses to the presentation of both CS-types alone (not followed by shocks) will be investigated. We predict increased arousal to the CS+, but not the CS-, presentation.

Study burden and risks

The main burden for the participant consists of having to undergo six presentations of the electric shock. This will startle the participants. However, the intensity of the shocks will be tailored to the participant*s pain threshold in a work-up procedure that involves the presentation of shocks at increasing levels until the participant experiences the shock as uncomfortable but not painful. In addition, an electric current of 0.5 Volts will be maintained between the electrodes measuring the elctrodermal response. The risk

of being exposed to an electric current in case of short circuiting is minimal, because patient safe conditions will be maintained. Time investment will be only a single visit of 1 - 1.5 hours. This research will yield an insight into the role of odors as possible triggers of fear and subsequent symptoms in humans, a topic about which still little is known.

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

Students who are 18 years or older, are generally healthy, do not have a psychiatric condition or anxiety disorder, epilepsy, heart condition, a pacemaker, who are not pregnant or possibly pregnant, have a good (self-reported) sense of smell, no severe allergies, no asthma, and no scores of 4 or higher on 3 or more items of the modified Chemical Intolerance Index (which is indicative of MCS), will be accepted into the study. Participants who have a severe cold or the

flu at the moment of the lab visit will be rescheduled.

Exclusion criteria

Students who are younger than 18 year, who are not generally healthy, who have a psychiatric condition or anxiety disorder, who have either epilepsy, or a heart condition, or a pacemaker, who are pregnant or possibly pregnant, have a bad (self-reported) sense of smell, who have severe allergies, or asthma, or scores of 4 or higher on 3 or more items of the modified Chemical Intolerance Index (which is indicative of MCS), will be not accepted into the study. In addition, participants who have a severe cold or the flu at the moment of lab visit will not be included in the experiment that same day.

Study design

Design

Study type: Observational invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL25646.041.08