Return of fear and the role context: comparing a visual to an olfactory context: Studies 1, 2 and 3

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

Summary

ID

NL-OMON30903

Source
ToetsingOnline

Brief title
Return of fear and context

Condition

- Anxiety disorders and symptoms

Synonym
anxiety disorders

Research involving
Human

Sponsors and support

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

Intervention

Keyword: classical conditioning, context, fear, olfaction

Outcome measures

Primary outcome

The CS is a line drawing presented on a computer screen. The US is a loud noise (50 msec of 95 dBA of white noise) with sudden onset and offset presented directly following the CS via a headphone, which will startle the participant.
Per study, 50 participants will be tested (n=100 in total). As dependent variable, the electrodermal response will be measured via electrodes attached to the palmar surface of the hand, as well as the extent to which participants expect to receive the US, which they can indicate on a visual analog scale. In Study 3, the dependent variable of interest is the interval of uncertainty, or the part of the spectrum of colours associated with the CS that is evaluated as identical to the CS.
Finally, questionnaires will be administered containing question about demographics, an evaluation of the context(s), and attention for odour.

Secondary outcome

Questionnaires will be administered with demographhic questions, questions about evaluation of context, neurotcism and attention for odours.

Study description

Background summary

Specific phobias may result from learning by classical 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). By means of exposure therapy, in which the patient is exposed to the CS without ever receiving the US, fear may be extinguished. However, fear can return after successful exposure. One of the variables involved in this return is context. If extinction takes place in a context that is different from the context in which fear was originally acquired, return to the acquisition context may result in renewal of fear.

Study objective

In this research study the role of context in extinction will be investigated in healthy adults in a laboratory setting. Renewal of fear will be compared in two contexts of different modality: a visual context (the illumination of the room) and an olfactory context (an odour matched to the illumination contexts). The research questions are 1) does a previously extinguished fear return upon return to the acquisition context, and 2) are there any differences in this phenomenon, depending on the modality of the context (visual or olfactory)? In Study 3, the relation between personality (neuroticism) and memory for the CS will be investigated.

Study design

Two experimental studies related to context will be conducted: one with illumination condition as context, and a second with odour as a context. Healthy students of the social sciences, 18 years and older will be recruited for these studies. Every study consists of three main phases: acquisition (pairing the CS to a US), extinction (presenting the CS without the US), and a test phase in which the reaction to the CS is tested. In the experimental condition, participants will return to the acquisition context after having received extinction in a different context B (ABA). In the control condition the three contexts will remain the same. In Study 1, A refers to *lights on*, and B to *lights off*. In Study 2, A and B refer to different odors each. We hypothesize that in case of a return from the extinction context B to the acquisition context A, the electrodermal response will increase as a sign of renewed fear, and the expectation to receive the US will also increase. These changes are not expected in the control condition where no change of context occurs.
In a third Study, the acquisition phase will be followed by a memory test, to investigate whether persons high on neuroticism have a less accurate recollection of the CS than persons low on neuroticism.

Study burden and risks

The main burden for the participant consists of having to undergo eight presentations of the electrical shock which will startle the participants. The level of the shock is self-selected in a special procedure in which the

participant recives increasing levels of the shock and slects the level that he/she considers as unpleasant yet not painful, which procedure takes individual differences into consideration. Since application of shocks higher than the maximum of 4 mAmpere and 500 msec duration are made impossible, participants can not be exposed to dangerous levels or durations of the shock. 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 hours.This research will yield an insight into conditions in which extinction as a result of exposure therapie is effective, and into the role of odours as possible triggers of fear 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, hearing-aid, a good (self-reported) sense of audition and vision, who are not pregnant or possibly pregnant, will be included in Study 1 will be accepted into the study.For inclusion in Study 2, in addition to the above, they need to have with a good (self-reported) sense of smell, no severe allergies, no asthma, or scores of 4 or higher on odour sensitivity, and not to have a severe cold or the flu .
For inclusion in Study 3, students will be preselected on their scores on Eysenck's Personality Inventory, and need to be in the upper or lower quartile in order to qualify for inclusion. They will also need to meet all other criteria. Thus, students who are high in neuroticism cannot have a diagnsoed anxiety disorder.

Exclusion criteria

Participants who are younger than 18, indicate not to be healthy in general, to have a psychiatric conditions, or, specifically, anxiety disorders, epilepsy, a heart condition, pacemaker or hearing-aid, to have a below-average sense of smell, audition or vision, to be pregnant or possibly pregnant will not be included in any study. If they have severe allergies, asthma, odor sensitivities, or have a severe cold or flu they will not be included in Study 2. Study 3: Student whose scores on the Eysenck's Personlity Inventory does not fall into the upper or lower quartile of the neuroticism scale do not qualify. Those who do fall into the above quartiles need to meet all other criteria for the Studies 1 and 2. If they are high on neuroticism, they cannot be diagnosed with an anxiety disorder.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2007
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-12-2008
Application type:	Amendment
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	NL17107.041.07