Fear generalization: a direct replication of Lissek et al. (2010)

Published: 24-03-2020
Last updated: 08-04-2024

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

Summary

ID

NL-OMON49639

Source
ToetsingOnline

Brief title
Fear generalization

Condition

- Anxiety disorders and symptoms

Synonym
Panic, Panic disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: ZonMW and NWO. The study has been awarded via the Replication grant

Intervention

Keyword: Conditioning, Generalization, Memory, Panic disorder

Outcome measures

Primary outcome

Electromyography (EMG) responses and reported risk ratings for each CS and GS.

Online risk ratings and reaction time for the risk ratings. Both

electromyograph responses and risk ratings will be used to test between-group

differences in the course of learning.

Secondary outcome

A self-report of anxiety levels after the main experiment will be used for

testing between group differences. The Panic Disorder Severity Scale (Shear et

al. 1997), State-Trait Anxiety Inventory (Spielberger et al. 1983) and Beck

Depression Inventory (Beck et al. 1996) will be used to test for between group

differences before the beginning of the study.

Study description

Background summary

Panic disorder is a prevalent and chronic anxiety disorder characterized by reoccurring panic attacks (Kessler et al., 2006). Panic attacks are sudden, often unexpected periods of intense fear, that can be accompanied by physical symptoms like sweating, trembling, shortness of breath, chest pain, or others (American Psychiatric Association, 2013). Fear is often caused by anxiety or the anticipation of danger. However, prior research has shown that such fear may not always be associated with only the stimuli that had been previously associated with a panic attack (e.g. getting a panic attack while being in the gym, so now the gym is predictive of a panic attack), but generalized to similar stimuli (e.g. all types of gyms). Lissek et al. (2010) have researched this fear generalization and found that individuals diagnosed with panic disorder generalize fear more readily than healthy controls. Their findings led

to numerous experimental and clinical studies, but no direct replication of this study has been done yet. However, replication of Lissek et al. (2010) is urgently needed for at least three reasons. First, an unpublished direct replication of the initial study design was unsuccessful. Second, Lissek et al.*s (2010) results are already being used in research that attempts to block or reduce fear generalization. Because of this, it is important to determine whether generalization has a role in panic disorder indeed and consequently whether relevant intervention studies may be useful for reducing panic symptomatology. Third, since a single lab replication is often not sufficient to assess the replicability of a study, the current research will replicate the study across multiple labs. In accordance with Lissek et al. (2010), we predict that participants with panic disorder will show more generalized avoidance compared to control subjects.

Study objective

The main goal is to test whether individuals with a panic disorder diagnosis differ in the level of fear generalization compared to matched controls. This would be a direct replication of the seminal study by Lissek et al. (2010).

Study design

This study will be a blinded between-subject study employing individuals with a panic diagnosis and healthy matched controls.

Intervention

This study uses a fear generalization procedure consisting of three phases: pre-acquisition, fear acquisition, and a generalization test. In the pre-acquisition phase participants will see a small and a large circle. During the acquisition phase, the smallest and largest circles will serve as CS+ (the danger cue) and CS- (the safety cue), counterbalanced. One of these circles will be followed by shock administration (CS+), and the other circle is not followed by a shock (CS-). In the generalization test phase, participants see both CSs, as well as eight intermediate circles (generalization stimuli; GSs). Fear responses will be measured primarily by measuring startle responses, via electromyography (EMG), to a loud noise during the CS and GS presentations. Additionally, risk ratings as well as the accompanying reaction times (RT) will be collected by asking participants to estimate the level of risk during the experiment, with the available answers being 1 = no risk, 2 = moderate risk, and 3 = high risk.

Study burden and risks

During the experiment, participants will receive electrical stimulations, that can be described as being uncomfortable, but not painful. Benefits for panic

patients as a whole are that this study may provide important information on the change processes that occur in fear generalization. Understanding how fear generalization works could be crucial in understanding the acquisition of panic symptomatology. In addition, this study will be one of the first direct replication of clinical study, something that will provide important new guidelines towards better designing direct replications of studies with clinical populations.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Comparison subjects have to be free of any current or past axis I psychopathology as assessed by the Structured Clinical Interview for DSM-IV-TR, Patient Edition (SCID; American Psychiatric Association, 2000). Participants in

the experimental condition have to be free from current major depressive disorder, a current or past history of bipolar depression, psychosis and delusional disorders, and they must be diagnosed with a panic disorder. All participants should be between 18 and 65 years old and should be capable of making a reasoned review of their interest with regard to the research, i.e. giving informed consent.

Exclusion criteria

A history of alcohol or substance abuse or dependence (other than nicotine) within 6 months before study start; current (possible) pregnancy; cardiovascular problems or disease; trouble seeing (unless corrected by glasses or contact lenses); trouble hearing (unless corrected by hearing aids); an electrical implant (such as a pacemaker, ICD or neurostimulator).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2021
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	24-03-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-02-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL69799.041.20

Study results

Date completed:	01-09-2022
Actual enrolment:	3

Summary results
Trial is onging in other countries