Fear inhibition in PTSD patients; a fear-potentiated startle paradigm

Published: 08-11-2007
Last updated: 09-05-2024

In order to provide additional evidence and to verify the proposed impaired fear inhibition, validation is needed in a clinical sample of anxiety disorder patients. In the present study, inhibition of fear of PTSD patients will be compared with...

Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders
Study type	Observational invasive

Summary

ID

NL-OMON31162

Source
ToetsingOnline

Brief title
Fear inhibition in PTSD patients

Condition

- Psychiatric disorders

Synonym
Anxiety disorder, post traumatic stress disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: AX+/BX- fear conditioning paradigm, fear inhibition, PTSD, startle response

Outcome measures

Primary outcome

1. *Startle* respons is measured by exposure to the *startle probe*. Door middel van deze respons wordt de mate van angst en uiteindelijk de mate van inhibitie gemeten. De *startle probe* (akoestische stimulus) wordt binauraal door een koptelefoon geleverd. De *startle probe* bestaat uit een witte ruis (alle frequenties omvattende) geluidsstimulus met een geluidsdrukniveau van 104-dbA en een duur van 40 msec.

2. Cognitive expectancy/contingency awareness: the online US expectancy is measured on a 11- point scale from certainly no electrical pulse to uncertain to *certain a elektric pulse'. After every stimulus presentation the online expectancy is registered.

3. Propositional knowledge: after the computertask is finished the questionnaire about the obtained knowledge about the stimuli are answered.

Secondary outcome

Using the human fear conditioning paradigm it is demonstrated that the effects of extinction are largely confined to the context in which the extinction procedure took place (Vansteenwegen, Hermans, Vervliet et al., 2005).
From the clinical viewpoint, it is suggested that changes in the constellation of the therapy context contribute to the sometimes reported Return of fear

(Rachman, 1989) following successful therapy completion (see also Bouton, 2002)

Bouton and colleagues (e.g. Bouton & Nelson)

For these reasons, the effects of context on (transfer of) inhibition

performance will be tested. It will be hypothesized that patients with PTSD

will show less transfer of inhibition to another test context than controls. In

other words, patients regard the safety cue in another context as less

inhibitory.

Study description

Background summary

There is substantial evidence that neuroticism or trait anxiety poses a risk factor for the development of anxiety disorders, but the mechanism remains unclear. It is often assumed that mechanisms underlying experimental fear conditioning play a fundamental role in the aetiology and maintenance of anxiety disorders. Therefore, studies using fear-conditioning paradigm will provide essential insights in the underlying mechanisms of pathological anxiety and as a consequence, acquired knowledge could lead to improved treatment techniques. The prevailing hypothesis that may account for the etiological contribution of trait anxiety states that it may give rise to increased excitatory fear learning. Although this hypothesis is appealing, evidence for this hypothesis is scarce. As children grow up, they normally experience a range of fears that wax and wane following a predictive pattern. The presence of fears is not restricted to the vulnerable children. It is hypothesized that the transition from normal fears to anxiety disorders may be better explained by impaired fear inhibition of the fear-response even in the presence of safety signals than by increased fear acquisition. A crucial element of anxiety may be the distrust of safety signals instead of the overestimation of threat stimuli.

Study objective

In order to provide additional evidence and to verify the proposed impaired fear inhibition, validation is needed in a clinical sample of anxiety disorder patients. In the present study, inhibition of fear of PTSD patients will be compared with trauma exposed non-PTSD individuals. This patient group can be depicted by excessive anxiety and a failure to overcome these emotions. Impaired fear inhibition could be related to the onset or maintenance of these

symptoms. It is predicted that patients with PTSD will show impaired fear inhibition in a fear-potentiated startle paradigm (AX+/BX). If patients with PTSD show impaired fear inhibition, this provides further evidence for the mediating role of impaired fear inhibition in the etiology of anxiety disorders.

Study design

This study embrace a clinical experimental study design. In order to test the fear inhibition hypothesis, a recently developed AX+/BX- procedure (Myers & Davis, 2004; Jovanovic et al., 2005) was used that allows for an independent evaluation of excitation and inhibition of fear.

Fase Component
Habituation [NA (4)]¹
[NA (4)]²
Conditioning fase [AX+ (6)]¹
[BX- (6)]¹
[NA (6)]
Testfase 1 [AB- (3)]¹ of [AC- (3)]¹
[NA (3)]¹
Re-conditioning fase 1 [AX+ (3)]¹
[BX- (3)]¹
[NA (3)]¹
Testfase 2 [AC- (3)]¹ of [AB- (3)]¹
[NA (3)] ¹
Re-conditioning fase 2 [AX+ (2)]¹
[BX- (2)]¹
[NA (2)]¹
Testfase 3 [AB- (3)] ²
[NA (3)] ²

[]¹ = context 1, light
[]² = context 2, dark
CS+ = with US (electric pulse)
CS- = without US
NA = *noise alone*
AX+ = color combination followed by adverse stimulus (US)
BX-., AB, AC = color combination not followed by adverse stimulus (US)

Study burden and risks

Although some people could experience the experiment as aversive, the experiment involves no risks,the burden is minimal and the computer task only takes 25 minutes.

Contacts

Public
Universiteit van Amsterdam

Roetersstraat
1018 WB Amsterdam
Nederland
Scientific
Universiteit van Amsterdam

Roetersstraat
1018 WB Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All subjects have experienced a work-related trauma. The main inclusion criteria for the experimental group is to meet the DSM IV criteria for PTSD as a consequence of a work related trauma.

Exclusion criteria

The main exclusion criteria all subjects are; severe concentration problems, visual problems, hearing problems, pregancy, cardiovascular complaints and epilepsy. ;Exclusion criteria for the experimental group is severe comorbidity and PTSD as a consequence of complex trauma. Exclusion criteria of the control group are any DSM IV diagnosis.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL19049.018.07