Positive and negative consequences of military deployment to Afghanistan.

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In the current study we will prospectively investigate whether pre-trauma differences in expectancy learning and evaluative conditioning, and posttrauma differences in inhibitory learning predict PTSD symptoms at follow-up. A larger US-expectancy…

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

Summary

ID

NL-OMON35403

Source
ToetsingOnline

Brief title
Consequences of military deployment.

Condition

- Anxiety disorders and symptoms

Synonym
Posttraumatic stress disorder, psychotrauma

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: NWO (Nederlandse Organisatie voor Wetenschappelijk Onderzoek);Open MAGW Program. Project title Learning;reasoning;and trauma (project nr 400-07-181);period September 15;2008 to September 15;2012;awarded to Prof. Dr. I.M. Engelhard).

Intervention

Keyword: Evaluative conditioning, Expectancy learning, Inhibitory learning, Posttraumatic stress disorder

Outcome measures

Primary outcome

Differences in fear-learning that are already present before deployment between soldiers who develop PTSD symptoms and those who do not, after deployment. These differences are revealed in US-expectancy patterns during the differential conditioning task and the US-expectancy bias task, and differences in reaction times at the affective priming task. In addition, study parameters are differences in inhibitory learning shortly after deployment, revealed through differences in startle reactivity, skin conductance and US-expectancy in response to the inhibitory learning task. Posttraumatic complaints and other psychological complains are assessed using a self-report questionnaire and a semi-structured interview.

Secondary outcome

Questionnaires will be administered to assess demographics characteristics, psychological and physical symptoms (including problems related to anger and alcohol use), personality features (including neuroticism, extraversion, worry, anxiety sensitivity, intolerance of uncertainty, and frustration intolerance), deployment-related variables (support within unit, stressors on earlier deployments), life-events, and positive experiences (positive experiences of deployment, perceived growth).

Study description

Background summary

Anxiety disorders may be the result of learned fear through the process of classical conditioning. In classical conditioning, a neutral stimulus is paired with a neutral, unconditioned stimulus (US), which causes fear. When the neutral stimulus gets associated with the US, the neutral stimulus itself provokes fear as a conditioned stimulus (CS), triggering the expectancy of the US. This process is called expectancy learning. Expectancy of the US, and consequently fear associated with the CS, is thought to extinguish if the CS is no longer associated with the US. This can be achieved by exposure to the CS without the US or by exposure to the US alone. A recent breakthrough in de understanding of fear is that fear extinction results from new learning (Cs-no US), instead of elimination of the original fear association. This new learning is referred to as inhibitory learning. Another process in classical conditioning is evaluative learning, which refers to a change in the intrinsic valence of the neutral stimuli in a US-valence congruent direction. Individual differences in both evaluative conditioning and expectancy learning may play an important role in the development and maintenance of PTSD. More specifically, this is thought to involve a larger US-expectancy bias during acquisition, reduced extinction of the US-expectancy, and larger hedonic shifts in the evaluation of the CS.

Study objective

In the current study we will prospectively investigate whether pre-trauma differences in expectancy learning and evaluative conditioning, and posttrauma differences in inhibitory learning predict PTSD symptoms at follow-up. A larger US-expectancy bias during acquisition and extinction, and stronger evaluative conditioning may be pre-trauma vulnerability factors for the development of PTSD.

Study design

Prospective study including a pre-assessment, post-assessment, and follow-up. In the first assessment, participants are administered computer tasks, starting with the differential conditioning task consisting of six phases: the stimulus selection phase, habituation phase, acquisition phase (pairing of CS+ to US, CS- to no US), extinction phase (presenting CS without US). The conditioning task is followed by an affective priming task to measure evaluation of the CS, and finally a US-expectancy bias task. In the second assessment, a similar conditioning task (*inhibitory learning task*) will be administered, consisting of a habituation phase, acquisition phase, and transfer of inhibition phase. During all assessments, participants are administered questionnaires. At the

second and third assessment, a semi-structured clinical interview takes place (SCID; PTSD and Axis-I disorders).

Study burden and risks

The burden consists of 8 mild electrical stimuli (500 ms, 0.2-4.0 mA) during the conditioning task and two brief loud burst of noise (500 ms, 95 dB) during the expectancy bias task, which will be completed before deployment. During the inhibitory learning task administered after deployment the burden consists of 12 mild electrical stimuli (500 ms, 0.2-4.0 mA) as well as 45 brief bursts of noise (40 msec, 108 dB). Possibly, the participant could have an excessive fear reaction on the electrical stimulus. However, using a work-up procedure, the stimulus is set at an individual level that is *unpleasant and demanding some effort to tolerate, but not painful*. The stimuli are not dangerous. These procedures are used worldwide without any aversive reactions. The loud noise could be fearful for some participants. There could be some inconvenience while filling in the questionnaires about psychological complaints, personality and anger. The participant can choose to not fill in the question. The participant could get upsetdescribing deployment related traumatic events. In case of undesirable emotional reactions, the researcher or assistant will be available to provide help.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Royal Dutch Army soldiers of the battle groups who are being deployed to Uruzgan, Afghanistan.

Exclusion criteria

Soldiers will be excluded who already completed the conditioning tasks used in previous studies conducted by prof.dr. Engelhard. (MEC 04-217). Such prior experience will likely influence the results. The other exclusion criterium is color blindness. We do not use other exclusion criteria, as we wish to include a representative sample of soldiers who are deployed to Uruzgan.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-08-2009
Enrollment:	230
Type:	Actual

Ethics review

Approved WMO Date:	30-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-06-2010
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL26645.068.09