

Developing Intrusive Memories after Trauma: an experimental study on the effects of endocrine stress reactivity

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

Summary

ID

NL-OMON47527

Source

ToetsingOnline

Brief title

The effects of stress on involuntary memories

Condition

- Anxiety disorders and symptoms

Synonym

posttraumatic stress disorder, trauma

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ZonMw veni subsidie

Intervention

Keyword: cortisol, PTSD, trauma, vulnerability

Outcome measures

Primary outcome

Differences between stressor and control condition in: salivary cortisol and alpha amylase output as measured six times during the experimental paradigm and the total frequency of intrusive memories during the 7 days following the experimental paradigm.

Secondary outcome

- Differences between stressor and control condition in accuracy of voluntary memory and characteristics of intrusive memories related to the trauma film.
- Associations between baseline glucocorticoid receptor functioning, cortisol and alpha amylase stress reactivity during the experimental paradigm and voluntary memory accuracy and intrusive memory frequency and characteristics.

Study description

Background summary

To improve prevention of posttraumatic stress disorder, it is important to increase our understanding of the biological and cognitive mechanisms underlying the development of its hallmark symptom, i.e. intrusive memories. Individual variation in endocrine stress reactivity to the traumatic event, resulting in decreased contextual memory processing, is thought to underlie intrusive memory development. Studying these process in more detail is only feasible in healthy individuals using an experimental trauma paradigm. However, the best currently available paradigm, the trauma film paradigm (consisting of watching a film with aversive graphic footage of traumatic events) does not result in consistent activation of the two most important stress systems, i.e.

the autonomic nervous system and hypothalamic-pituitary-adrenal axis, limiting ecological validity of this paradigm and therefore hampering reliable investigations into intrusive memory development. Therefore, the aim of this study is to adapt this trauma film paradigm, which is expected to result in more robust endocrine stress responses and increased frequency of intrusive memories.

Study objective

The primary objective is to investigate whether adding a brief mild psychosocial stressor (socially-evaluated cold pressor test) immediately prior to an experimental analogue traumatic event (trauma film paradigm) increases acute endocrine stress reactivity (salivary cortisol and alpha amylase output) throughout the experimental paradigm and increases intrusion frequency in the following week. Secondary, it will be investigated whether addition of a stressor affects voluntary memory accuracy and intrusion characteristics related to the trauma film. Furthermore, the impact of individual variation in endocrine stress reactivity throughout the paradigm and glucocorticoid receptor functioning on voluntary and intrusive memories related to the trauma film will be investigated.

Study design

Randomized controlled trial

Intervention

Half of the participants will be randomized to the stressor condition, i.e. the socially-evaluated cold pressor task, consisting of immersing their hand into ice cold water while being videotaped for evaluation. The other half of the participants will be randomized to the control condition, in which they immerse their hand into lukewarm water without being videotaped. Thereafter, all participants will watch a trauma film, known to induce intrusive memories in the following week.

Study burden and risks

The study consists of three assessments, and include the experimental procedures described above, questionnaires, cognitive tasks and non-invasive assessment of biological stress reactivity. Additionally participants will collect saliva for endocrine assessments at home for two consecutive mornings and will fill out a short diary about intrusive memories for 7 consecutive days. Study participants will not benefit from the research, and may experience some short lived discomfort from the cold pressor task. Additionally, they will likely experience some distress resulting from the trauma film and resulting intrusive memories, which is however expected to have disappeared at one week

follow-up. The study is classified as moderate risk.

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

- Male sex;
- Age 18-40 years;

Exclusion criteria

- Current major medical disorder;
- Current use of medications known to impact endocrine stress reactivity;

- Lifetime psychiatric diagnosis;
- Current significant anxiety or depressive symptoms;
- Current significant PTSD symptoms;

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2017
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO	
Date:	27-02-2017
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	NL60305.018.16