The biological stress-system in sexually assaulted female adolescents with PTSD and its response to cognitive behavior therapy

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Major objectives:1. To measure basal salivary cortisol and DHEA(S) levels and salivary cortisol responses to low-dose dexamethasone in sexually assaulted adolescents with PTSD compared to cortisol and DHEA(S) values in non-traumatized controls. 2....

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

Summary

ID

NL-OMON31810

Source
ToetsingOnline

Brief title
Biological stress-system in sexually assaulted girls with PTSD

Condition

- Anxiety disorders and symptoms

Synonym
Post Traumatic Stress Disorder, responses on sexual assault

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: NWO Mozaiek project nummer 017.002.112

Intervention

Keyword: cognitive behavior therapy, HPA-axis, Post Traumatic Stress Disorder, sexual assault

Outcome measures

Primary outcome

biological parameters: cortisol, DHEA(S), sAA

PTSD symptoms

Secondary outcome

other trauma-related symptoms such as depressive symptoms, anxiety symptoms,

sexual concerns, cognitive and concentration problems, somatic complaints,

agressive behaviour and dissociative complaints.

Study description

Background summary

Sexual assault, including rape, is a gender-specific crime that disproportionally affects female adolescents. Half of adult female victims of sexual assault suffer from Post Traumatic Stress Disorder (PTSD) after three months and 30-45% still do so after 1 year. Prospective data in PTSD in female adolescents have not been studied. The biological correlates of sexual assault have received little attention in research. Since sexual assault is a highly stressful experience, it is hypothesized that there is an association with the functioning of the body*s stress systems, such as the Hypothalamic Pituitary Adrenal (HPA)-axis and the (nor)adrenergic system. Three products of these systems will be addressed in girls who have been sexually assaulted and compared with non-traumatized controls: salivary cortisol, DHEA(S), and salivary alpha amylase (sAA).
If PTSD is associated with dysregulated neuroendocrine measures, these measures would hypothetical *renormalize* if the PTSD is treated successfully in cognitive behavioral therapy (CBT). In this study, the association between PTSD reduction and changes in neuroendocrine variables will be measured.
Studying the relation between clinical and biological changes in sexually

assaulted adolescents after CBT can provide more insight into the causal mechanism of the HPA-axis dysregulations found in victims of sexual assault. Also, results from this study can identify the potential to changeability of these dysregulations after CBT and may enlarge pharmacological treatment possibilities of PTSD. Finally, results of this study may help to discriminate PTSD patients who are less responsive to CBT and, hence, may require other interventions.

Study objective

Major objectives:

1. To measure basal salivary cortisol and DHEA(S) levels and salivary cortisol responses to low-dose dexamethasone in sexually assaulted adolescents with PTSD compared to cortisol and DHEA(S) values in non-traumatized controls.

2. To measure the association between PTSD reduction and changes in cortisol and DHEA(S) levels of sexually assaulted adolescents with PTSD in response to trauma-focused CBT.

3. To determine the predictive value of salivary cortisol and DHEA(S) in PTSD patients at baseline for successful CBT

4. The measure the correlation between self-rated subjective distress in PTSD patients in response to the trauma narrative and the amplitude of the cortisol response and sAA response.

5. To determine the predictive value of the amplitude of the cortisol response and sAA response to the trauma narrative for successful CBT.

Study design

A cross-sectional study will be carried out in 100 sexually assaulted adolescents with PTSD and in 100 age- and gender-matched non-traumatized control subjects (recruited from secondary schools in the Utrecht area). History of sexual trauma in the control group will be assessed with checklist questionnaires. The patient and control group will be compared on salivary cortisol and DHEA(S) output after awakening and at 5 pm and with respect to a dexamethasone suppression test (DST).

A prospective study will be carried out in 50 sexually assaulted adolescents with PTSD (subgroup of the above mentioned 100 patients) who will receive Cognitive Behavior Therapy (CBT) according to STEPS, individual or in group. At post-treatment (T2), at 6 month follow-up (T3) and at 12 months follow-up (T4), adolescents and parents will be re-assessed according to the standardized psychological assessment procedure. Also, salivary cortisol and DHEA(S) output

after awakening, at 5 pm and cortisol response to DST will be determined again at T2, T3 and T4. The association between PTSD reduction and changes in neuroendcorine variables will be measured.

In 30 patients with PTSD (subgroup of the above mentioned 50 patients who will be provided STEPS) who followed the STEPS group treatment, saliva will be collected in every patient during the session of trauma narrative exposure. Salivary alpha amylase (sAA) will be assessed in this saliva and related to treatment outcome.

Intervention

At the Psychotrauma Center for Children and Youth in Utrecht (UMC Utrecht), a CBT protocol has been developed for sexually assaulted adolescents with PTSD and their parents, named STEPS. Details of the STEPS protocolized treatment are being published (Bicanic & Kremers, 2007). STEPS incorporates several intervention techniques also used in the effective cognitive behavior treatment protocols, such as psycho-education, writing assignments, trauma narrative, exposure in vivo and cognitive restructuring. STEPS can be administered individually or in a group. The group treatment consists of eight weekly sessions of two hours each and includes a parallel parents* group. STEPS targets at reducing PTSD symptomatology.
A recent pre-post pilot study in the Trauma Center in Utrecht showed a clinical and statistical significant improvement after group STEPS in 34 raped adolescent girls at post-treatment and at 6- and 12-month follow-up with respect to reduced levels of PTSD, anxiety and depression.

Study burden and risks

In the Netherlands, 1 in 6 girls between the age of 12-25 have experienced forced sex (De Graaf et al, 2005). A part of this group seriously suffers from this trauma and is impeded in development. It is essential to gain more knowledge on the process of (biological and psychological) recovery after sexual assault. In order to gain knowledge on functioning of the stress-system in assaulted and raped girls with regard to the effects of psychotherapy, it is inevitable to collect saliva by salivettes at different moments before and after therapy. Collecting saliva is a non-invasive and easy method, that can be performed at home. We expect no physical risk from sampling saliva and from taking dexamethasone. A low dose < 1,0 mg dexamethason should be enough to show suppression (Ebrecht, 2000). When a low dose dexamethason is taken orally, no serious side-effects are expected. In clinical practice it is common to start with 0.75 - 15 mg dose daily and this dose is used for a longer period of time. Possibly, girls who have been raped orally (5-10% of all referrals) might experience problems with taking the salivette in their mouth. In case of oral rape, the patient will be asked if participation is doable.
De burden of the research is saliva collection and the dexamethason suppression

test for all patiënten with PTSD as a result of sexual assault. For a subgroup who received STEPS treatment, saliva collection and dexamethason suppression test will be repeated directly after treatment and at 6-month and 12-month follow-up. From this subgroup, saliva will be collected in those who receveid group treatment coording to STEPS, durong the trauma narrative exposure session.
The researchers believe that performing the reserach is justified, after taking into account the burden and risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Involvement in sexual assault on one occasion with one or more persons, > 1 month post-assault, ages 13-18, PTSD and IQ >85.

Exclusion criteria

Exclusion criteria include a history of child abuse and/or previous sexual assault, psychotic or organic mental disorder, schizofrenia, alcohol or drugs addiction.

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):	29-04-2008
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	26-02-2008
Application type:	First submission
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	NL18706.041.07