PTSD in children: underlying mechanisms and treatment

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1. Examine the physiological, endocrinological and neural differences between children with PTSD and without PTSD2. Examine if neurobiological treatment effects of TF-CBT and EMDR differ and if so how3. Examine if neurobiological treatment effects...

Ethical review	-
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON36199

Source
ToetsingOnline

Brief title
PTSD in children

Condition

- Anxiety disorders and symptoms

Synonym
Post-traumatic stress disorder, stress complaints

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Frijling Prins Fonds

Intervention

Keyword: children, neurobiology, Post-traumatic stress disorder, psychotherapy

Outcome measures

Primary outcome

Neuroimaging: (f)MRI, DTI,

Physiological measures: Heartrate(variability), Skin conductance

Endocrinological measures: Cortisolconcentration in saliva

Secondary outcome

CAPS-CA (interview to help diagnose PTSD)

ADIS (interview to screen for anxiety disorders)

cPTCI, RCADS, CRIES, SDQ, Kidscreen

Study description

Background summary

Every day, children suffer from assault, sexual abuse, natural disasters, accidents or other traumatic events. The prevalence of traumatic events in children is high. While most children will recover from exposure to a traumatic event without developing a post-traumatic stress disorder (PTSD) a significant minority (10 up to 35 percent) will develop PTSD in the aftermath of a traumatic event. PTSD is a disabling and often chronic anxiety disorder which has short and long term negative influences on (mental) health, social life and academic functioning. When a child develops PTSD, effective treatment is essential. Trauma focused cognitive behavioral therapy (TF-CBT) and EMDR have shown promising results in children. Most children benefit from psychotherapy but a substantial part of children does not demonstrate symptom remission during the course of treatment. There is insufficient insight in the mechanisms which are involved in the development of PTSD and treatment response. These insights can help to indentify children who are at risk of developing PTSD, improve precision of referrals and improve treatment strategies, especially for treatment non responders. Research in adults has shown that PTSD and response to psychotherapy are associated with changes in neural circuitry involving frontal and limbic structures. Furthermore changes in the hypothalamus

pituitary adrenal (HPA) axis and autonomous nervous system (ANS) have been found. These results are however not easily extrapolated to children and adolescents mainly because these neurobiological systems are still fully developing during childhood and adolescence and do not reach functional maturity before adulthood. Therefore studies using neurobiological measures in children with PTSD are warranted.

Study objective

1. Examine the physiological, endocrinological and neural differences between children with PTSD and without PTSD
2. Examine if neurobiological treatment effects of TF-CBT and EMDR differ and if so how
3. Examine if neurobiological treatment effects are maintained over a longer period of time
4. Examine the relationship between psychometric, neuroimaging, physiological and endocrinological measurements
5. Examine if neurobiological measures can be used to predict treatment response and relapse after treatment

Study design

This project consists of two consecutive parts: One part is a cross-sectional comparison between children who are exposed to a traumatic experience without developing PTSD and children who do develop PTSD. The following neurobiological measures will be conducted: neuroimaging, endocrinological and physiological measurements.
In a longitudinal part we will administer the above mentioned biological measures only to the participants with PTSD. We will utilize a PROBE design (prospective randomized open label blinded endpoint). Measurements will be conducted at three time points; three months after the most recent traumatic experience (before treatment has started), after completion of treatment and six months post-treatment. Each measurement point consists of two appointments, one for the physiological measures and one for the neuroimaging procedure.

Intervention

Participants with PTSD will randomly be assigned to one of the following to treatments as part of the study by Diehle (MEC 09/076). For both treatment conditions 8 sessions of 60 minutes will be implemented.
TF-CBT: The components included in the protocol for TF-CBT are: psychoeducation and Parenting skills; Relaxation; Affective modulation; Cognitive coping and processing; Trauma narrative; In vivo mastery of trauma reminders; Conjoint child-parent sessions; Enhancing future safety and development.
EMDR: The following components are included in the protocols: psychoeducation and preparation; assessment; desensitization; installation; body scan; positive

closure and enhancing future safety.

Study burden and risks

Participation in the study does not hold any risks. However, subjects have to spent time to participate in the study. For traumatized controls this means spending 3,5 hours in the study; children with PTSD will spend 6 hours in participation. For children with PTSD, the time consumed will be kept low by combining appointments for research participation with appointments they have in the scope of the regular patient care at De Bascule. This eliminates time spent travelling.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Involvement in at least one traumatic event
Age 8 through 17 years

Exclusion criteria

- Acute suicidal
- Mental disorders due to a general medical condition
- Meeting the criteria of one of the following DSM IV TR-diagnosis: psychotic disorder, substance use disorder, pervasive develop disorder (e.g. autism), mental retardation
- Known presence of a significant medical illness including cardiac arrhythmias and epilepsia
- Pregnancy
- Gross obesity (weight greater than 150% of ideal body weight) or growth failure (height under 3rd percentile)
- The use or presence of medication with central nervous system or HPA axis effects within the 2 weeks before measures
- Claustrophobia
- Presence of any metal or electrical conductive implants or foreign bodies

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2011
Enrollment:	120
Type:	Actual

Ethics review

Not available

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	NL35971.018.11