Effects of Trauma Focused Cognitive Behavioural Therapy (TF-CBT) and Eye Movement Desensitization and Reprocessing (EMDR) for children with Posttraumatic Stress Symptoms

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The main objectives of the present study are: determining short and long term effects of TF-CBT and EMDR; assessing the efficiency of these therapies; and identifying the characteristics of those children who do not respond to the given treatment.

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

Summary

ID

NL-OMON35682

Source
ToetsingOnline

Brief title
Effects of TF-CBT and EMDR for children with PTSS after trauma

Condition

- Anxiety disorders and symptoms

Synonym
Posttraumatic Stress Symptoms, stress complaints

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Frijling Prins fonds

Intervention

Keyword: children, cognitive_behavioral_therapy, emdr, posttraumatic_stress_disorder

Outcome measures

Primary outcome

The primary study parameters are the scores on the CAPS-CA post treatment

compared to the baseline scores (delta).

Secondary outcome

The secondary parameters are the scores regarding comorbidity on the ADIS C/P,

the scores on the RCADS, CRIES, SDQ, NOSI-K and the CPTCI immediately, six and

twelve months post treatment as well as scores on the Kidscreen 12 months post

treatment.

Study description

Background summary

Many children get involved traumatic events. The exposure to a traumatic event may lead to post traumatic stress symptoms. Evidence based treatments for children are needed to prevent long term impairment.

Study objective

The main objectives of the present study are: determining short and long term effects of TF-CBT and EMDR; assessing the efficiency of these therapies; and identifying the characteristics of those children who do not respond to the given treatment.

Study design

The study design is a randomized comparison of TF-CBT and EMDR. A waiting list condition may be added from a comparable study which will be conducted by prof. dr. Goldbeck at the university of Ulm.
It concerns an open label study, meaning that the treatment condition is known to the therapist and the patient. However to prevent biases, the researcher who conducts the CAPS-CA interviews will not be informed about the treatment condition (PROBE design: prospective randomized open label blinded endpoint).

Intervention

Treatment is either given in form of 8 sessions TF-CBT or EMDR.

Study burden and risks

Treatment for traumatized children involves both, TF-CBT and EMDR at the Bascule. As such this is not unusual and there are no more risks associated with the participation in this study as there are associated with regular treatment. In fact both therapies aim at the reduction of post traumatic stress symptoms and children benefit from either treatment.
The two follow-up measures at 6 and 12 months after the completion of the treatment mean an extra burden. At both moments children are asked to participate in interviews and complete some questionnaires. This will take approximately 2 hours.
Furthermore, while treated, participants are asked to fill in a questionnaire (CRIES) every two weeks. This will take about 5 minutes.

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 a single or multiple traumatic event(s).
Duration of posttraumatic stress symptoms lasts three months or longer.

Exclusion criteria

Coma
Acute suicidality
Mental disorder due to a general medical condition
Meet the following DSM IV TR diagnoses:
psychotic, drug abuse, developmental disorder

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2009
Enrollment:	150
Type:	Actual

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	NL26870.018.09