Eye Movement Desensitization and Reprocessing (EMDR) in children with a medically related trauma

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29358

Source
Nationaal Trial Register

Health condition

EMDR, PTSS, PTSD, medical trauma, trauma, congenital heart disease, emergency department, aangeboren hartafwijking, SEH

Sponsors and support

Primary sponsor: ErasmusMC Sophia Children's Hospital Rotterdam, the Netherlands
Source(s) of monetary or material Support: InnovatieFonds
Stichting Hartekind
Vereniging EMDR Nederland

Intervention

Outcome measures

Primary outcome

PTSD symptoms (SVLK >60 percentile)

Secondary outcome

Anxiety (SCARED-NL)

Depression (CDI-II)

Quality of Life (TACQOL)

Sleep (SSR)

Self-Perception (SPPC)

Attention problems (CBCL, TRF)

School functioning (CBCL, TRF)

Medical consumption/adherence

Study description

Background summary

Around 1 in every 10 children admitted to the hospital for undergoing an invasive and painful medical procedure develops a posttraumatic stress disorder (PTSD) and circa 3 in every 10 children develop a partial/subclinical PTSD. Although PTSD is associated with unfavourable medical and mental health outcomes, children are often not structurally screened on PTSD. If PTSD symptoms are left untreated, this may harm the child’s quality of life and psychosocial functioning. Currently, cognitive behavioural therapy (CBT) is the most evidence-based intervention for PTSD. A new innovative treatment is Eye Movement Desensitization and Reprocessing (EMDR), which is less intensive, is less burdensome for patients, works faster and is thus cheaper compared to CBT. This is the first RCT to investigate the direct effectiveness of standardized EMDR in children with medically related trauma. Therefore we will include all consecutive patients who underwent one or more admissions to the ErasmusMC Sophia Children's Hospital and who are 6-16 years old between July 2016 – July 2017, encompassing:

1) previously healthy children (with no underlying illness/handicap) admitted to the hospital for the first time after an unexpected emergency with no comorbidity (trauma type I) and

2) patients with congenital heart disease admitted for a recurrent procedure (trauma type II; e.g. surgery).

Patients with PTSD symptoms are allocated to: a) EMDR or b) care-as-usual CAU. All patients will receive adequate medical care (CAU).

Study objective

1) EMDR will lead to significant improvement of psychosocial functioning, quality of life and somatic complaints in children with elevated PTSD symptoms (subclinical/partial PTSD).

2) Children with unfavourable predictors (low socioeconomic status, less adequate coping) will benefit more from EMDR as compared to children with favourable predictors.

Study design

Pre-post assessments (T1,T2) and a 6 months
follow-up assessment (T3)

Intervention

Eye Movement Desensitization and Reprocessing (EMDR). EMDR is a standardized treatment method for trauma, consisting of a structured nine-phase approach to address the past, present, and future aspects of a traumatic or distressing memory. The EMDR treatment will consist of six weekly sessions of 1 hour.

In this study the active control group will receive care as usual, which means they get the regular medical care.

Contacts

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Eligibility criteria

Inclusion criteria

The target group of this study consists of:

1) children and adolescents (6-16 years old) suffering from a partial (subclinical) PTSD due to one, sudden and unforeseen event, that occurred at least 4 weeks up to maximally three years ago, such as a traffic accident or severe acute illness. We include children who -after consultation at the emergency department at our hospital-, were hospitalized for the first time and underwent invasive diagnostic procedures and/or treatment; and

2) children and adolescents (6-16 years old) suffering from (subclinical) PTSD due to invasive, repeated traumatic events of which these children/adolescent's know these events may happen again. We include children/adolescents with congenital heart disease, who underwent a repeated invasive medical procedure or examination (e.g. heart surgery or heart catheterization), at least 4 weeks up to maximally 3 years ago.

Exclusion criteria

1) Mental retardation.

2) Inability to read or write Dutch.

3) Previous treatment for PTSD.

4) A score below the 60th percentile on the SVLK

5) A clinical score on the Clinician Administered PTSD Scale for Children and Adolescents (CAPS-CA)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2016
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-05-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47373
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5665
NTR-old	NTR5801
CCMO	NL56156.078.16
OMON	NL-OMON47373

Study results