# Treatment of PTSD in children

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21205

**Source**
NTR

**Health condition**

Posttraumatic stress disorder (PTSD)

### Sponsors and support

**Primary sponsor:** Prof. dr. R.C.M.E. Engels
Behavioural Science Institute, Radboud University Nijmegen
**Source(s) of monetary or material Support:** ZonMw

### Intervention

### Outcome measures

**Primary outcome**

PTSD symptoms, self-report by child: UCLA PTSD Reaction Index (PTSD-RI)

**Secondary outcome**

Child measures

- PTSD symptoms: PTSD section of the K-SADS-PL; UCLA PTSD Reaction Index (PTSD-RI)

- Depressive symptoms: BDI-II

- General functioning: SCARED; PedsQL; GCI; #schooldays

- Dissociative symptoms: dissociation section of the BPD-47

- Social support after the trauma happened

- Disclosure of the traumatic event

- Avoidance: PABQ

Parent measures, about psychopathology of the child

- PTSD symptoms: UCLA PTSD Reaction Index (PTSD-RI)

- General functioning: PedsQL; GCI

Parent measures, about own psychopathology

- General functioning: GCI; OQ-45.2; BDI-II

- PTSD symptoms: PSS-SR (about possible own traumatic events and about the traumatic event of the child)

- Avoidance: PABQ

# Study description

**Background summary**

The present study aims to examine the effectiveness of a brief intensive exposure therapy for children with PTSD. The new treatment program makes use of proven effective therapy techniques in processing the trauma and decreasing PTSD symptoms in children, whereas the delivery of the treatment is using a new format: one week of intensive trauma-focused treatment while including a trauma-related social support program for family members.

Country of Recruitment: The Netherlands

**Study objective**

The present study aims at the improvement of the treatment of children with PTSD by examining the effectiveness of a brief intensive exposure therapy (IET) for children with PTSD using a multiple baseline design (patients are randomly assigned to baseline length).

**Study design**

Time points of primary interest (primary outcome)

Weekly during:

- Baseline length (varying from 4 to 8 weeks before treatment)

- Treatment length (5 weeks)

- Post treatment length (varying from 4 to 8 weeks after treatment)

- Follow up length (during 4 weeks, 3 months after treatment)

Time points secondary outcomes

- before treatment (A0)

- three weeks after baseline (A1)

- three months after baseline (A2)

- and six months after baseline (A3)

**Intervention**

Brief intensive modified exposure therapy and a trauma-related social support program for family members:

5 days (one week), offered in three blocks of 90 minutes each day and up to three follow up appointments (90 minutes each)

# Contacts

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# Eligibility criteria

## Inclusion criteria

(1) Current DSM-IV diagnosis of PTSD established with the PTSD section of the Kiddie-Schedule for Affective Disorders and Schizophrenia-Present and Lifetime Version (K-SADS-PL)

(2) Age between 7 and 18 years (boys & girls)

## Exclusion criteria

(1) Psychosis or delusion disorders (current or in the past)

(2) Suicidality

(3) Mental retardation

(4) Substance abuse or dependence or alcohol abuse or dependence

(5) Insufficient ability to speak and write Dutch

(6) Trauma caused by a caregiver who is part of the current primary care system

(7) Current DSM-IV diagnosis of PTSD of the caregiver established with a structured diagnostic interview (M.I.N.I.) and the PTSD Symptom Scale Self-Report (PSS-SR)

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-12-2012 |
| Enrollment: | 10 |
| Type: | Actual |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 02-12-2013 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL4149 |
| NTR-old | NTR4301 |
| Other | *ZonMW & **CCMO : *80-82470-98-006-04 & **NL36971.091.11 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A