

# Prevention of post-traumatic stress disorder in children and adolescents

<b>Submission date</b> 22/01/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 22/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 24/01/2007	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

## Study objectives

Risk of chronic Post-Traumatic Stress Disorder (PTSD) after Acute Stress Disorder (ASD) diminishes with an early intervention (Cognitive Behavioural Therapy [CBT]) that attempts to modify cognitive appraisals.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approval received from the Medical Ethics Commission academic hospital of Maastricht /Maastricht University (Medisch Ethische Commissie azM/UM) on the 11th October 2006 (ref: 06-3-045).

## Study design

Randomised, crossover, single blind multicentre trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Post-Traumatic Stress Disorder (PTSD)

## Interventions

Brief trauma-focused cognitive behavioral therapy intervention or control-condition (wait-list-controls).

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

1. Presence versus absence of PTSD
2. PTSD-symptom-severity, assessed with:
  - a. structured interview (Anxiety Disorders Interview Schedule for Children [ADIS-C])
  - b. self-completed questionnaires (Child Post-traumatic Stress Scale [CPSS])

### **Secondary outcome measures**

Symptoms of anxiety and/or depression according to questionnaires (Revised Children's Anxiety and Depression Scale [RCADS]) and quality of life.

### **Overall study start date**

01/12/2006

### **Completion date**

01/01/2008

## **Eligibility**

### **Key inclusion criteria**

1. Children (aged seven to 17)
2. Had contact with Victim Assistance experiencing a traumatic event less than two weeks ago
3. Meet the Diagnostic and Statistical Manual of mental disorders (DSM) criteria for Acute Stress Disorder

### **Participant type(s)**

Patient

### **Age group**

Child

### **Lower age limit**

7 Years

### **Upper age limit**

17 Years

### **Sex**

Not Specified

### **Target number of participants**

80

### **Key exclusion criteria**

1. Brain injury
2. Psychotic or organic mental disorder
3. Current suicidal ideation
4. Intelligence Quotient (IQ) less than 80
5. Low proficiency in Dutch
6. No parent willing to participate in the study

**Date of first enrolment**

01/12/2006

**Date of final enrolment**

01/01/2008

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**University Maastricht**

Maastricht

Netherlands

6200 MD

## **Sponsor information**

**Organisation**

University Maastricht (UM) (The Netherlands)

**Sponsor details**

P.O. Box 616

Maastricht

Netherlands

6200 MD

**Sponsor type**

University/education

**Website**

<http://www.unimaas.nl/default.asp?taal=en>

**ROR**

<https://ror.org/02jz4aj89>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

**Alternative Name(s)**

Netherlands Organisation for Health Research and Development

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Netherlands

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration