

Prevention of post-traumatic stress disorder in children and adolescents

Submission date 22/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/01/2007	Condition category 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

Contact name
Dr Manon J B Vincken

Contact details
University Maastricht
Department of Medical, Clinical and Experimental Psychology
P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 388 1047
m.vincken@dmkep.unimaas.nl

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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])

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

17 years

Sex

Not Specified

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration